Exhibit T

Redacted

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

- -

Michelle Simha, as Trustee for the Next-of-Kin of Noah Leopold,

Plaintiff,

Civil File No. 24-CV-01097-JRT-DTS

vs.

Mayo Clinic,

Defendant.

- -

DEPOSITION OF MAURICIO VILLAVICENCIO

Volume I, Pages 1 - 153

August 14, 2024

(The following is the deposition of Mauricio Villavicencio, taken pursuant to Notice of Taking Deposition, via video, at Mayo Clinic, Legal Department, 100 Second Street SW, Rochester, Minnesota, commencing at approximately 1:15 p.m., August 14, 2024.)

APPEARANCES:
On Behalf of the Plaintiff:
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ALSO PRESENT:

Ron Huber, Videographer
Anna C. Messerly, Ciresi Conlin
Maggie Palmisano, Ciresi Conlin (via Zoom)
Sheri Peterson, Mayo Clinic
Michelle Simha (via Zoom)
Norman Leopold (via Zoom)
Karen Leopold (via Zoom)
Jenna Shulman (via Zoom)

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P R O C E E D I N G S

THE VIDEOGRAPHER: We're on the record. Today is August 14th, 2024. The time is 1:15 p.m. Today's case caption is Simha versus Mayo Clinic. The witness for today's deposition is Mauricio Villavicencio.

At this time the court reporter will swear the witness.

(Witness sworn.)

MR. BRANTINGHAM: Brandon, I'm sorry, before you proceed, can I just --

I just want to put on the record that I -- that I provided the emails to you --

MR. THOMPSON: Oh, sure.

MR. BRANTINGHAM: -- that I believe completes the production of responsive emails from Dr. Villavicencio. Obviously we'll talk about anything about that further, I just wanted to put it on the record --

MR. THOMPSON: Sounds good.

MR. BRANTINGHAM: -- lest I forget when it happened.

MR. THOMPSON: Sounds good.

MR. BRANTINGHAM: Please proceed.

MAURICIO VILLAVICENCIO,

called as a witness, being first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. THOMPSON:

Q. All right. Doctor, have you ever had your deposition taken before?

A. No.

Q. So just a couple of quick ground rules to make sure that we get on the same page and we get a nice, clean record.

Number one, try to keep your voice up. You're a little bit of a soft talker so far. It makes the court reporter's job easier if you can speak as loudly as you can. Okay?

A. Sure.

Q. Let's try really hard not to talk over one another. I'm bad about that, as we've established over the course of the last few days, but I'm going to try hard not to talk over you and you try hard not to talk to over me. Okay?

A. Sounds good.

Q. Verbal responses like yeses and nos are really good; shakes of the head and nods and

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grunts or uh-huhs and huh-uhs are not good because they're hard to take over on the transcript. So make sure you respond verbally. Okay?

A. Okay.

Q. If any of my questions are in any way unclear, will you promise to let me know so I can rephrase my question and make sure you and I are on the same page?

A. Sure.

Q. All right. You're the director of the heart/lung transplant program here at Mayo; is that right?

A. Yes, sir.

Q. Tell me a little bit about the transplant program.

A. Well the lung transplant program has been very successful in the recent years since I came and we have achieve great results and we have transplanted way more people than was before maintaining excellent outcomes, so we're kind of proud in terms of clinical experience per year. We count the experience per year. We're around 10th in the nation for volume.

Q. For lungs or hearts?

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A. For -- for both.

Q. What year's statistic are you using there that you're 10th in the nation in volume?

A. 2023, 2024. So I have managed to boost the program since I arrived 2021. Before we were like 40 in the nation, --

Q. And there --

A. -- something like that.

Q. I'm sorry.

There again you're talking about volume, number of transplants.

A. Number of transplant and outcomes.

Q. So when a transplant program is being evaluated, --

A. Uh-huh.

Q. -- number of transplants is an important metric and outcomes is an important metric; right?

A. Yes, sir.

Q. When we're talking about outcomes, we're talking about the one-year survival outcomes?

A. That's one of the metrics. There are several metrics.

Q. What is --

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What are the most important survival metrics to you as the director of the program here?

A. Ninety-day survival as in the surgical side, but it matters to me most what happens in the long run. For example, in the last scientific registry of transplant recipients we have the highest survival three year of follow-up in the country.

Q. Are you talking about for heart or lung?

A. For heart.

Q. Where does --

When you say "we," are you talking just about Rochester, or are you talking about Jacksonville, Arizona, and Rochester together?

A. Rochester only.

Q. All right. So where does Mayo Rochester rank in terms of one-year survival statistics for heart transplant?

A. Average in the nation.

Q. Average.

A. Uh-huh.

Q. Do you know why that is?

A. It's around 90 percent, 90, 92 percent

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at a year.

Q. No. Sorry.

Do you have an idea of why Mayo is just average when it comes to one-year survival?

A. Because we have excellent outcomes, so, you know, there's half of the country that's below us.

Q. Sure. But there's also half of the country that's above you.

A. Yeah. But you could filter your results to get them better and do low-risk patients and not transplant anybody.

Q. So with --

A. So it's excellent results, sir.

Q. With respect to volume, when we talk about volume being an important metric, we're talking getting the volume numbers up. Right?

A. Yeah. So that people don't die from heart failure.

Q. Sure. Where does Mayo --

You said 10th in the nation in volume?

A. Yes, sir.

Q. Just for heart.

A. Yes.

Q. And that's just --

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A. Not for lung, too.
Q. Let's stick just with heart. Okay?
A. Okay.
Q. I'm going to focus --
A. I haven't say anything about lung, but you asked me.
Q. I'm going to focus really specifically on heart transplant --
A. Uh-huh.
Q. -- for purposes of our discussions today.
So your testimony is that with respect to the heart transplant program, Mayo Rochester is 10th in the nation in volume.
A. Correct.
Q. Where was it when you started here when you took over the program?
A. Thirty, 40, somewhere in there.
Q. I -- I assume that you're proud of the fact that you've increased the numbers of transplants?
A. Yeah. Proud of the fact of saving lives by heart transplantation.
Q. My question was: Are you proud of the fact that Mayo's volume numbers have gone up?

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A. I answered your question. I'm proud of the fact that when we increased the volume, save heart-failure patients from death.
Q. Tell me about your involvement with TransMedics.
A. I -- I start using TransMedics during the clinical trials at the Massachusetts General Hospital in Boston when I was a -- an attending heart transplant surgeon at the Mass General Hospital.
Q. That was your first involvement with TransMedics?
A. Yes. I'm not sure 2015, maybe the end of, because I started September 2015. For sure I would say in 2016, eight years ago.
Q. And so back then your involvement with TransMedics was being involved in the PROCEED trial?
A. No. I was the --
In the EXPAND trial. The PRO -- the PROCEED trial had already been done.
Q. That's right. That was doctors mostly at UCLA?
A. Yeah, UCLA, some people in Europe, Columbia.

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Q. Was the EXPAND trial funded by TransMedics?
A. Yes.
Q. Is that the only research study you've been involved in that was funded by TransMedics?
A. No, I -- I --
In heart -- we're talking about heart only again --
Q. Yes.
A. -- on this case, so in the -- then the -- the postmarket-approval registry is funded and mandated by the FDA. I'm the principal investigator here at the Mayo Clinic for that.
Q. You're the principal investigator you said?
A. Yes.
Q. How much money does TransMedics provide to Mayo for that?
A. I don't -- I don't know exactly. It's minimal enough to, you know, maintain the record.
Q. More than a hundred thousand dollars?
A. I don't know.
Q. What other --

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You mentioned something about lung. Have you had involvement with TransMedics for lung as well?
A. Yeah. I participated in the EXPAND trial. So in the case in the Mass General I was the co-investigator -- co-investigator for the EXPAND trial, but in the -- the lung side I was the principal investigator for the EXPAND trial in -- for, you know, this, you know, FDA-regulated trial.
Q. And so both of those were funded exclusively by TransMedics.
A. Yes.
Q. Have you ever met the CEO of TransMedics?
A. Yes.
Q. How many times?
A. Several times.
Q. More than ten?
A. Probably. I don't know. I don't count how many times I meet people.
Q. Okay.
A. Maybe 30 times.
Q. Thirty times.
A. Maybe. I don't know. I don't count

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them. I'm guessing.
Q. Have you ever traveled on a -- and had that funded in any way by TransMedics?
A. Yeah. I have traveled to the investigative meetings I think twice.
Q. Where were those meetings?
A. One was in -- in Saint Thomas and one was in Boston, not very long travel from home.
Q. TransMedics funded a meeting in Saint Thomas, the Virgin Islands?
A. Yes, sir.
Q. And paid for you to travel there?
A. Yes.
Q. Any --
A. Oh, and there was one in the --
So there's two, that one and there's one in -- I think they did one in the -- in Nassau, I think in Bahamas.
Q. In the Bahamas.
A. Uh-huh.
Q. Got it.
And TransMedics paid for you to go there, too.
A. Yes, sir.
Q. Any other ways that TransMedics has

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provided you with any sort of financial benefit?
A. No, I have not receive any consulting fees.
Q. Do you have --
A. Nothing other than travel and accommodation for these two meetings and the Boston one.
Q. Where did you stay in Saint Thomas?
A. I -- I stayed in the Ritz-Carlton in Saint Thomas.
Q. How about when you went to the Bahamas on TransMedics' dime?
A. What was it? Atlantis, I believe.
Q. Both very nice places.
A. Yeah. Been more than five years since then.
Q. Sure.
Any plans for TransMedics to have meetings with these new studies that are going on?
A. I haven't heard any. There was --
There were meetings of the investigators, I think, last year. I didn't go.
Q. Why not?
A. In Boston.

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Because I'm -- I didn't find it interesting and I didn't have trip days.
Q. Didn't have what?
A. Trip days.
Q. Trip days. Got it.
A. So like the time that I can get out of -- of the Mayo Clinic.
Q. Yep. Got it.
When TransMedics flew you to the Virgin Islands and the Bahamas, did they fly you first class or coach?
A. Coach.
Q. You got to fix that for the next time.
Do you have stock in TransMedics?
A. No.
Q. Do you know -- well you --
I assume you know that one of the things that the SRTR tracks is selectivity statistics.
A. No.
Q. Are you aware of that?
A. No.
Q. Okay. So then I would assume that you have no idea how Mayo Rochester matches up with other institutions in terms of selectivity.

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A. What do you mean by "selectivity?" I haven't heard about that term before in heart transplantation.
Q. Well so, for example, one of things that SRTR tracks is offer-acceptance characteristics. Do you know that?
A. Oh, yeah. Yeah.
Q. Yep.
A. I wouldn't call that selectivity.
Q. Well so do you know what the offer-acceptance ratio refers to?
A. Yeah. It was --
It's better than in the nation.
Q. My question was: Do you know what the offer-acceptance ratio is?
A. I can't remember the number, --
Q. No, no.
A. -- but I just can remember our relationship to the nation, that it was better than, you know, the whole nation.
Q. Well "better than," you mean that Mayo accepts a lot more organs than other institutions do?
A. Yeah.
Q. One of the things that I read in some

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materials that were put out by Mayo is a quote that says, "We say yes when others say no." Have you heard that little catch phrase?

A. Yeah.

Q. Do you believe in that catch phrase?

A. We try to do everything that is medically possibly to improve the patients' lives --

Q. Uh-huh.

A. -- and save them from death.

Q. Yeah. No, my question was just: Do you subscribe to that little catch phrase, "We say yes" --

A. Well it -- it --

Q. You got to --

Hold on. Hold on. Doctor, you got to let me finish.

MR. BRANTINGHAM: Yeah. Let him finish the question after and then -- then you go.

Q. Do you subscribe to that catch phrase, "When other" -- I guess it's "When others say no, we say yes?"

A. It's a slogan. I am not in the Marketing Department.

Q. Do you know where Mayo Rochester ranks

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in terms of the ratio of taking high-risk hearts?

A. You mean high-risk of -- in terms of the Public Health Service?

Q. Yes.

A. So in terms of risk of viral infection?

Q. Yes.

A. I -- I think it's -- I --

I'm not sure. You know, I don't have the report on my side here, but I think it was probably twice as in the country, something like that. I can't remember. Maybe you have it there.

Q. Yeah. Two and a half times --

A. Yeah.

Q. -- the national average in terms of --

A. Yeah.

Q. -- taking hearts that are considered high risk.

A. No. You are -- you are saying it wrong. It's increased risk of viral infections --

Q. Increased risk. Got it.

A. -- by the Public Health Service.

Q. Mayo takes more than twice as many

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hearts with an ejection fraction below 60 as the national average; right?

A. I don't know. I don't remember.

Q. Okay. If I told you that the latest statistics for SRTR was that Mayo took more than three times as many hearts from donors over the age of 40, does that sound about right to you?

A. Yes, sir.

Q. And almost four times as many hard-to-place hearts as the national average?

A. Yes.

Q. And more than double the number of donors from more than 500 miles away?

A. Yes.

Q. Now in order to do that, --

A. Uh-huh.

Q. -- you got to use the OCS; right?

A. Yeah. In part.

Q. Well you can't go get a donor heart from more than 500 miles away using just standard cold cardioplegia; can you?

A. Well it depends because, you know, other centers might choose to use another preservation method, SherpaPak, for example, and they -- I've heard about a report that the Mass

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General went to Alaska and got a heart from Alaska with cold storage --

Q. Huh.

A. -- with SherpaPak.

Q. Does Mayo use the SherpaPak?

A. No. It was on the shelf, but I haven't used it. I used it when I was in the Mass General. I wasn't the director of the program at that time.

Q. Is there a different director of the transplant program at Mayo Jacksonville?

A. Yes.

Q. And a different one at Mayo Arizona?

A. Yes.

Q. Do you know why the offer-acceptance ratios at the other two Mayo institutions are so much lower than Rochester's?

A. I don't --

In general terms, they -- you know, it's just -- I'll put it on the general word -- probably they are more conservative.

Q. Do you remember the Noah Leopold case?

A. Yes, sir.

Q. Do you have like a lot of memories of it or just a few?

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A. I have a lot of memories.
Q. Do you consider the Noah Leopold case to have been a failure?
A. It's unfortunate that a patient would die.
Q. That wasn't my question though.
Do you consider the Noah Leopold case to have been a failure?
A. I -- I think it's unfortunate a patient would have die.
Q. Is --
A. If you want to quote it as failure, that's you -- what you say, not what I say.
Q. No. I'm asking if you agree with it though.
A. Then I don't agree with it.
Q. Okay. You don't agree that it was a failure.
A. No.
Q. Do you agree that what happened to Noah Leopold was a catastrophe?
A. I don't think so.
Q. No?
You just think it was unfortunate.
A. It was a tragedy and unfortunate.

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Q. Okay. Do you remember talking with either Dr. Altarabsheh or Dr. Knop from the operating room?
A. Do you mean when they were in the operating room with the donor?
Q. Yeah. So let me ask it a little tighter way. There's some text messages sent in this case that --
A. Uh-huh.
Q. -- suggest that one --
You're aware of those text messages.
A. What?
Q. You're nod --
I started saying "text messages" and you nodded your head and said "uh-huh" like you're aware of what I'm talking about.
A. No, I'm -- no, I'm --
People might have sent text messages. I normally do not communicate like that.
Q. Yeah.
A. I'm Chilean, you know, I use very little text messaging.
Q. Are you aware of the fact that there are a number of text messages that have been produced that are relevant to this case?

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A. Yeah, I -- I think the -- this gentleman here next to me, Mr. --
MR. BRANTINGHAM: Brantingham.
A. -- Brantingham, I don't know how to pronounce it, --
MR. BRANTINGHAM: Andrew's fine.
A. -- you know, show me some.
Q. Okay. Did you --
Have you seen the text messages that refer to either Dr. Altarabsheh or Dr. Knop telling you that the lactates for the donor heart for Noah Leopold were bad or terrible?
A. No. I -- I -- I -- I don't recall that. And if they say that, it's completely wrong because the lactates were excellent.
Q. No. I understand that. That wasn't my question.
You know that there are a number of text messages that suggest that you asked Dr. Altarabsheh and/or Dr. Knop about the lactates and they gave you the impression that the lactates were not good; right?
A. No.
MR. BRANTINGHAM: Object to the form and foundation. I'm frankly not sure he is. I

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mean if you want to show him --
MR. THOMPSON: Yeah, he might not be. That's fine.
A. I --
Q. Do you remember --
A. I mean if somebody says that, it's wrong. I don't care.
Q. Do you remember asking Michael Pick to go get the lactate values?
A. I always ask the perfusionist the lactate values.
Q. Okay. Do you remember anyone suggesting to you, before you saw the lactate values, that there was an issue with them?
A. There was no one.
Q. No one made such a suggestion to you.
A. No. There was no bad lactic acid --
Q. That wasn't my question.
A. -- volume.
Q. We'll talk about -- we'll talk about the lactates. I'm not asking whether there were bad lactates.
I'm going to show you Mayo 25074, first of all. Do you see that top text message?
Doctor, I'm asking you if you see the

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top text message.
A. Yeah, I see that, but I don't remember that. But he's wrong.
MR. BRANTINGHAM: Just -- yeah. So wait for the question and respond --
Q. You got to listen to --
MR. BRANTINGHAM: -- specifically to it.
A. All right.
Q. Nope. You hang onto that, because I'm going to ask you some questions from it.
A. Uh-huh.

[redacted]

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[redacted]

Q. Do you remember anybody saying anything to you about the heart not being robust --
A. I don't remem --
Q. -- while it was on OCS?
A. I don't remember that.
Q. If somebody had told you that the heart did not look robust while it was on OCS, would that have been noteworthy to you?
A. Of course I would review that.
Q. What do you mean you would review that?
A. Yeah. If somebody tells me that the -- that the heart is bad, that could be wrong or right, so I have to review it, look at it myself.
Q. You couldn't look at the heart until it came to the operating room; right?
A. Yeah. Could I look? No. I -- That is physically impossible.
Q. If the heart had been not robust, or "bad" to use your words, --

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A. Uh-huh.
Q. -- when it got to the operating room, it would have been too late; right?
MR. BRANTINGHAM: Object to the form, foundation. You can answer.
A. What do you mean by "too late?"
Q. By the time that donor heart got to the operating room, you had already taken Noah Leopold's heart out; right?
A. Yeah. Because we rely on the -- on the team that we sent to look at the heart. So -- so normally the -- the team looks at it at the donor site, then when they are about to take off and then when they land, so I talked to my team in that way. And then it is the best, the clinical practice, to start the case when the heart is meant to look good, and then as soon as they arrive, be ready to sew it in. So we minimize the time on the OCS to minimize the time of the heart out of the body.
Q. How long can the heart stay viable on OCS?
A. We don't know for sure.
Q. Do you remember giving a presentation where you talked that "Most people who have" --

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there's actually a slash here -- "Most people who've been involved with the OCS think that total body time can be eight hours or even more?"
A. It's possible, but the longer you are on the OCS, the more edema you could have on the myocardium. So the shorter time on the OCS, the better.
Q. How long does it take for a heart to get from the airport in Rochester to the operating room?
A. Fifteen minutes.
Q. So if you had wanted to, you could have waited 15 minutes to get your eyes on this heart before you took out Noah's heart.
A. I have trust in my team. They are competent professionals.
Q. Wasn't my question.
My question is if you --
A. I answer it.
Q. With respect, you didn't. My question wasn't do you have confidence in your team.
A. Yeah. But --
MR. BRANTINGHAM: Let him ask the question, doctor, and then you can answer.

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Q. My question was: Could you have waited if you wanted to?

A. Yeah. But that will be a bad clinical decision because you have to shorten up the time on the OCS.

Q. Do you remember doing a presentation with Dr. Paul Friedman from Mayo in July of 2023?

A. Yes.

Q. Do you remember that presentation?

A. Yes.

Q. What was it about?

A. About the techniques for heart transplantation, one, you know, the ex vivo heart perfusion.

Q. Yeah. Do you remember during that presentation saying to Dr. Friedman, "So what happens is, for a reason that we completely do not understand, the heart gets edematous, so you have to examine the heart before implanted to make sure you know that it hasn't gotten that edematous." Does that sound like something you would have said?

A. I don't remember exactly, but that doesn't mean to be by me, it means to be done by

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the surgical team. You know, it's impossible to work on -- on your own. You need to rely on your surgical team, and that was done.

Q. Who is Dr. Mohammad Alomari?

A. Mohammad? Who's that one?

Q. Do you recognize that name?

A. Mohammad?

Q. Yeah. One of your colleagues in Jacksonville, at Mayo Jacksonville?

A. I -- I don't think I know him.

Q. Dr. Pankaj Garg, does that name ring a bell?

A. No.

Q. Okay. John Yazji?

A. No.

Q. Dr. Wadiwala?

A. No.

Q. Well I'll tell you that all of those guys were involved in writing an article entitled "Is the Organ Care System Still the First Choice With Emerging New Strategies for DCD in Heart Transplant." Does that article ring any bells for you?

A. I -- I haven't heard about that study.

Q. I will tell you that in this article,

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written by your colleagues at Mayo Jacksonville, they describe the process for transplanting an OCS heart. And they say, "Once the heart reaches the recipient OR on the OCS machine, its contractility is reassessed. Based on heart function, other hemodynamic parameters, and lactate levels, if it is decided to proceed with the transplant, the first step is closure of the aortic vent," and yadda yadda yadda. Do you know whether your colleagues at Mayo Jacksonville wait until the heart arrives and can be reassessed in the operating room before they irreversibly remove the patient's native heart?

MR. BRANTINGHAM: Foundation.

A. I --

MR. BRANTINGHAM: You can answer.

A. I don't know if they wait.

Q. But you told -- but you told me before that it would be bad clinical practice to do that. Do you think your colleagues at Mayo Jacksonville are committing malpractice?

A. No. I don't -- -

MR. BRANTINGHAM: Foundation.

A. -- I don't think it's --

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MR. BRANTINGHAM: Hang on just one sec, doctor. Let me -- I have to get an objection out. Foundation. You can go ahead and answer.

A. Well I -- I think, as I said, that the longer the time on the OCS, you know, the worse the results. Whether how many minutes matter or not, you know, might be a matter of debate, it has not been determined, so I would not accuse them of malpractice. It is -- is they might have a different approach, but it's not proven that it's better or worse.

Q. Well didn't you tell me, when I asked you if you could have waited that 15 minutes, "Yes, I could have, but it would be bad clinical practice?"

A. Yeah, yeah. From my standpoint, I said, you know -- again, I'm going to repeat to you, maybe you're not listening -- the longer -- that the longer that you are on the OCS, the more edema you get. So it is, for me, preferable to, you know, be ready to sew the heart in once it arrives. And provided that you have trust on your surgical team, which I do.

Q. Let's go back to my question, though, because that wasn't my question.

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My question was: Didn't you tell me under oath a few minutes ago, when I asked you --

A. Uh-huh.

Q. -- if you could have waited, you said, "Yes, I could, but that would be bad clinical practice?"

MR. BRANTINGHAM: Let me just object -- object that I think that is quite explicitly reasking the exact same question you think you already asked, so asked and answered.

MR. THOMPSON: He didn't answer it.

Q. But go ahead.

MR. BRANTINGHAM: Go ahead.

A. Well I -- I think I would -- I would not do that because that would result in -- in a worse clinical result.

Q. Okay. Did you tell me that waiting would be bad clinical practice?

MR. BRANTINGHAM: I mean we can read back the transcript, but it's -- it's been asked and answered. Maybe one more time, go ahead and answer.

A. I would prefer not to wait to decrease the -- the edema on the heart.

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Q. Wasn't my question. I didn't ask you if you preferred to wait. I asked you if you remember telling me under oath that waiting would be bad clinical practice.

A. Well you are -- you are trying to bring up a controversy with my colleagues in Mayo Florida. I don't think that's appropriate. Maybe my words were not exactly right, but I think it's preferable to not let the heart get more edematous and to decrease the time on the OCS.

Q. Okay. So now you'd like to retract what you said earlier that it was bad clinical practice?

A. Well in -- in the terms that -- your legal terms maybe; in my -- in my clinical positive way probably is appropriate. But you understand one thing, I understand a different one because we have different backgrounds.

Q. I'm asking you for your own words, doctor. Do you think it would be bad clinical practice to wait or don't you?

A. I would not accuse a colleague of bad clinical practice.

Q. I wasn't asking you if you accused a colleague of anything.

A. Well that's what you're implying, so I am answering your question.

Q. Don't try to read into my implication. Just answer the question I'm asking.

A. I -- I answer it.

Q. No, you didn't.

MR. BRANTINGHAM: Hold on one sec, doctor. Should we read back the original answer so that we have clarity on --

MR. THOMPSON: No, because now he's going to --

MR. BRANTINGHAM: -- what was said?

MR. THOMPSON: -- because now he put -- I'm good. Do you have an objection?

MR. BRANTINGHAM: My objection I think is asked and answered.

MR. THOMPSON: Great. Thank you.

MR. BRANTINGHAM: Okay.

Q. Is it bad clinical practice to wait or isn't it?

MR. BRANTINGHAM: You can answer that question.

A. I -- I think it would produce more edema on the heart, so I would not do that.

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Q. That wasn't my question.

A. I answer your question.

Q. No, you didn't. You answered a different question that I didn't ask, and we're going to keep asking this question until you actually answer it.

A. Then I think it's not a --

Then I don't think so.

Q. You don't think it's bad clinical practice.

A. In legal terms, no.

Q. Okay. You just think it's not something you would do.

A. Yeah. I would not do clinically because I want the best result for my patient.

Q. And you think that doing that, waiting, can lead to worse clinical outcomes.

A. Yes.

Q. Are you going to call up your colleagues in Jacksonville and tell them, "Hey guys, what you're doing may lead to bad clinical outcomes, and since we care about saving patients' lives here at the Mayo Clinic, maybe you should think about doing it differently?"

MR. BRANTINGHAM: Object to the form of

the question and the foundation. You can answer.

A. This --

To say that, you know, I will have to -- I need to have a -- a study about the times on the OCS, and we don't have that so far in the literature.

Q. None of that was my question.

You told me that in your opinion, as the director of the heart/lung transplant program at Mayo Clinic Rochester, waiting until the heart arrives in the operating room before you explant the native heart leads to worse clinical outcomes. My question is: Are you going to contact your colleagues at Mayo Jacksonville and tell them, "Hey guys, what you're doing may lead to worse clinical outcomes?"

MR. BRANTINGHAM: Object to the form. You can answer.

A. I will not do that until there is a study that would, you know, resolve that question.

Q. Do you remember what this heart looked like when it came out of the box?

A. Yes.

Q. What did it look like?

A. Excellent function.

Q. What color was it?

A. Like the color of a heart, like yellow and red.

Q. Any oth --

Anything else you can describe for me?

A. There was some ecchymosis, you know, on the heart, that's meaning a little bit of bruising.

Q. Anything else you can describe for me?

A. The squeezing function was excellent.

Q. Did you notice, when the heart came out of the box, that it was larger than expected?

A. No, it was not larger than expected.

Q. When you tried to transplant it into Noah there was a significant size mismatch; was there not?

A. Yeah, that's -- there was a size mismatch. That doesn't -- it's not the same that -- larger than expected. It was a size mismatch, so because I'm a transplant surgeon, I made the surgical maneuvers to fix that, and those maneuvers were successful, and so it was

fine.

Q. How big of a size mismatch was there?

A. Thirty-percent different.

Q. And in your clinical view that is significant; right?

A. Well it's --

I have transplanted many hearts that have been larger than 30 percent successfully.

Q. My question was: Is a 30-percent size mismatch, in your clinical view, significant?

A. Yeah, it's significant.

Q. Did you think going into this surgery there was going to be a 30-percent size mismatch?

A. Yeah, because the -- the donor was larger, and that's good for the hemodynamics of the recipients. So the larger the size is, the hemodynamics are better after a heart transplantation.

Q. Do you remember talking with members of the Leopold family after this catastrophic failed transplant?

A. I -- I remember --

MR. BRANTINGHAM: Object to the form of the question. Go ahead, you can answer, doctor.

A. I -- I remember talking to them.

Q. Do you remember telling them that you knew right away that the heart was bruised and didn't look great, but by then it was too late?

A. Well it was -- was -- you know, had bleeding several hours after it was implanted. It was bruised at the beginning, but just as described in the operative note, it is mildly bruised as is in the usual OCS cases.

Q. Mr. Leopold's family is going to testify that you told them that you knew right away when that heart came out of the box that it was bruised and it didn't look great, but by then it was too late because Noah's native heart had already been explanted. If -- you got to let me ask my question -- if they testify that you told them that, are you going to deny it?

A. I -- I --

In terms of the timing, I'm going to deny it. Because what had happened is it was, you know, severely bruised. If you -- you know, this is a qual -- qualitative description, you know, more like a hematoma, so big-time bruising. That -- that's what I told them that, you know, happened several hours later as, you

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know, the transplant went through. But -- but the bruising was mild.

Q. And you're sticking right now with you thought the heart itself looked excellent when it first came out of the box.

A. Yes.

Q. When you accepted this heart for transplant, did you know about the donor's social and health history?

A. Yes.

Q. Did you know that the donor was a meth addict?

A. Yes, sir.

Q. Did you know that the donor had died of a meth overdose?

A. Yes.

Q. Did you know that the donor had died of an intracranial hemorrhage that was brought on by that meth overdose?

A. Yes.

Q. You know that heart transplant recipients of donors with intracranial hemorrhage have worse survival; right?

A. That has not been established clearly in the literature.

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Q. You wrote an article that literally has that as the title; right?

A. Yeah. But the title is one thing, and the other thing is how it -- how it looks like.

Q. How what looks like?

A. Because if you read --

I'm going to explain the -- the abstract. The abstract shows that in the United States over 6,000 patients have been transplanted with intracranial hemorrhage, so kind of two years' worth of heart transplant practice in the whole United States. So that obviously -- it should tell you that taking donors with intracranial hemorrhage is a standard practice. And if you -- 6,000 heart transplants. And then if you see the abstract with an academic eye, you will see the difference that was encountered was a one-percent difference, between, you know, 11.9 -- so 12 percent and 13-point-something percent, one percent difference. Not clinically significant, just the study signify significant. And one more issue with that is that when there's a comparison of intracranial hemorrhage versus other type of strokes, the groups are not

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matched in risk factors, so the difference could have been different risk factors. For example, the group with intracranial hemorrhage were older, so that could have been the reason of the one-percent difference.

Q. None of that was my question.

When you published that abstract with the title "Heart Transplant Recipients of Donors with Intracranial Hemorrhage Have Worse Survival," did you intend to say "Heart Transplant Recipients of Donors with Intracranial Hemorrhage Have Worse Survival, But It's Not Clinically Significant?"

MR. BRANTINGHAM: I just object to the form of the question. Go ahead.

A. The --

I was not the first nor the last author. So I -- I --

In terms that this was submitted to a meeting, I thought it was reasonable, but it's not something that could be accepted in regular clinical practice because that will leave many, many patients with no life-saving heart transplant.

Q. None of that was my question either.

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Let me try again. I'll try a different question.

With respect to the clinical significance of these findings, do you remember what the conclusion is in this abstract?

A. That -- that you need to be cautious with intracranial-hemorrhage donors.

Q. And matched carefully with the appropriate recipient; right?

A. And --

Yeah.

Q. Got it.

Were you involved in any informed-consent discussions with Mr. Leopold before this surgery?

A. Yes.

Q. When did you meet with him?

A. The day before the transplant.

Q. The day before the transplant?

A. Well I mean during the day. You know, the transplant was during the night, so that's what I mean, the day.

Q. Got it.

A. Actually I think it was -- you know, the transplant was in the night, so in -- in

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that. There's two days in "during the night," so in the -- that day of that night, the previous day of that night I talked to him and the family.

Q. Do you remember about what time that was?

A. Maybe 3:00 p.m. Maybe. I can't remember.

Q. Do you remember -- do you remember anything about the conversation?

A. I remember there was a kind of half-an-hour conversation and that they -- all their questions were answered.

Q. Did Noah have lots of questions?

A. Yes.

Q. Like what?

A. I don't remember.

Q. You don't remember a single one?

A. Like "How is the donor?" "It's a good donor."

Q. He asked "How's the donor?" and you said "It's a good donor?"

A. "It's a good donor."

Q. When he asked "How's the donor?" and you said, "Oh, it's a good donor," --

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A. Yeah.

Q. -- did he ask you any follow-up questions on that?

A. I don't remember.

Q. When he asked you "How is the donor?" and you said "Good donor," did you tell him "But we've got to consider this donor with caution because he had an intracranial hemorrhage?"

A. It is -- it is forbidden by UNOS policies to give healthcare information or mechanism of death --

Q. Right.

A. -- to the donor, so we would not discuss that.

Q. Okay. So what is your understanding of what your obligation is when you're providing informed consent?

A. It is to tell the patient about the procedure they are going to have.

Q. Is that it?

A. Yeah. The benefits and the risks.

Q. Benefits and the risks of what?

A. Of the procedure, meaning heart transplantation.

Q. Do you talk with them in the -- about

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the benefits and the risks of the organ that you're planning on implanting in his body?

A. We talked before the patient is listed, so we got a -- a surgical consult either by me or one of my heart transplant colleagues. And as -- and as I said, you know, I talked to the recipient, you know, before the transplant, as I said I did.

Q. Okay. None of that's my question.

My question is: When you had the conversation with Noah, did you talk with him about the benefits and risks, not of the overall procedure, but of the specific organ you were planning on implanting in his body?

A. Well they have already been consulted by the whole team about that for extensive and overwhelming period of time. So we normally would tell -- you know, ask if there are any further questions of what has been already discussed, because the patient had had many discussions with the cardiologist, with another heart surgeon and so on and so forth, so we, you know, don't want to be redundant, and then, you know, ask if there's anything new.

Q. Okay.

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A. In general terms. You know, I can't remember what I talked to him and the family, I just remember that it was a half an hour.

Q. This --

Discussions that he had had in the days and weeks prior to the discussion you had with him, nobody knew anything about the donor heart that was going to be implanted in him then; right?

A. Do you think we have a crystal ball or something about how the donor's going to be?

Q. Well that's exactly my point. You don't have a crystal ball, so you --

A. Yeah.

Q. -- nobody at Mayo would have been able to tell Noah anything about the risks and benefits of that specific organ until the morning of August 29th; right?

A. No. We could not tell the specific, as I -- as we said, because, you know, UNOS forbids that.

Q. UNOS doesn't forbid that and neither does the OPTN.

A. It's the same thing.

Q. Yeah.

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MR. BRANTINGHAM: Just hold on -- wait --
A. No, no. It does. It does.
Q. Is it --
A. It does forbid that.
MR. BRANTINGHAM: Hold on. Hold on. Hold on. Wait for a question.
Q. I'm going to ask a question.
MR. BRANTINGHAM: Wait for a question.
Q. The question --
So what is your basis for saying that you are forbidden from telling somebody that the donor died of an intracranial hemorrhage?
A. Because there's UNOS, you know, bylaws and then you cannot do that.
Q. Are you talking about the OPTN Guidance on --
A. On UNOS.
Q. Huh?
A. On UNOS.
Q. UNOS or OPTN?
A. Well it's the same thing.
Q. They're two different organizations; aren't they?
A. Well they overlap.

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Q. How so?
A. Because they take care of a heart tran -- I mean transplantation in the U.S.
Q. Well sure, so does LifeSource. Is LifeSource and the OPTN the same thing?
A. Yeah. So, no, they overlap.
Q. Wasn't my question. You keep telling me that UNOS and OPTN are the same thing.
A. Well --
MR. BRANTINGHAM: Hold -- just wait -- wait -- wait for him to get to an actual --
Q. You got to wait for the question.
MR. BRANTINGHAM: There's a lot of words before an actual question. Let all the words come, --
THE WITNESS: Okay.
MR. BRANTINGHAM: -- and then when there's a real question, answer that question.
THE WITNESS: Okay.
BY MR. THOMPSON:
Q. Is it really your testimony that OPTN and UNOS are the same thing?
MR. BRANTINGHAM: Object to form. Go ahead, doctor, you can answer.
A. Honestly, I'm not sure. They usually overlap.

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Q. Have you ever seen OPTN's Guidance for Donor and Recipient Information Sharing?
A. Yeah, I think I saw that.
Q. The guidance that --
Do you know what OPTN is?
A. Organ Procurement Transplantation Network.
Q. How do they relate to your practice?
A. So they establish kind of the framework of the practice, transplant practice.
Q. What OPTN says is that "Deceased donor information routinely shared with the recipients/recipient families should be limited to information required as part of the recipient informed consent process for transplantation." What part of that says you can't tell them that they died of an intracranial hemorrhage?
MR. BRANTINGHAM: I just object to form and note for the record the pat -- the witness is not being shown the document that is being read to him.
Q. I just read you the statement. What part of that --
A. No -- no --

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Q. -- says you can't tell them there's an intracranial hemorrhage?
A. I don't know the exact document that you have, but I've read that they can't be informed about the cause of death.
Q. You read that somewhere.
A. Yes.
Q. That you're prohibited from doing that.
A. Yes, sir.
Q. Do you have an understanding that what Minnesota law requires, when you're providing informed consent to a patient, is you have to give the patient all of the information that a reasonable patient in that person's position would find significant in making a decision about their own healthcare?
A. I don't know about that. I'm not a lawyer.
Q. Do you strive, when you are providing informed consent to patients, to give a patient all the information they would find significant?
A. Yes, we do that in the -- in the consult, official consult, surgical now before the patient is listed, --
Q. I'm --

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A. -- as Dr. Daly did.
Q. Yep. I'm sticking with your conversation. When you provided informed consent to Noah --
When Dr. Daly talked to Noah, Dr. Daly didn't know that this donor organ was going to be coming from a meth addict who died of an intracranial hemorrhage; right?
A. Yep. We -- we should not tell the patient that.
Q. Wasn't my question.
My question was: When Dr. Daly talked to Mr. Leopold, Dr. Daly didn't know that the heart was coming from a meth addict who died of an intracranial hemorrhage; did he?
A. Well he didn't know, --
Q. Did he --
A. -- but he knew that 20 or 30 percent of the donors are -- in the U.S. are from drug overdose, so we discuss that.
Q. "We" being who?
A. We, any transplant professional, you know, would know that 20 or 30 percent are from -- from a drug addict in the U.S. from drug overdose.

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Q. Which means that 70 or 80 percent of them do not come from a drug overdose; right?
A. Yes.
Q. Which means that, assuming that Dr. Daly had that discussion with Noah, Noah would have understood that there was a seven- or eight-out-of-ten chance that the donor for his heart would not have had a drug overdose; right?
A. Yeah, that is possible; however, the -- he was told about this was an increased-risk donor. And increased-risk donor, Mr. Leopold knew very clearly that it could be, you know, a drug addict, and -- and he consented for that and that's documented.
Q. Okay. So first of all, please listen to my question and just answer my question. My question didn't have anything to do with any of that.
A. Well I'm not going to answer what you want.
Q. Well you've got to answer my questions though.
A. Yeah. I did.
MR. BRANTINGHAM: Hold on, doctor.
Q. Just hang on. Hang on. Hang on.

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MR. BRANTINGHAM: Let him -- wait for the next question.
Q. Hang on. I know that you're a busy man. I know that you don't want to be here. I get that. I would like to go home to Minneapolis as well. This will go a lot more smoothly if you answer the questions that I'm asking. Just answer that question, then stop, let me ask another question rather than answering my question and then trying to read into where I'm trying to go with it and give me a bunch of other information that has nothing to do with the question that I asked. So --
A. I think the situation is different. I think the situation is that you don't like my answers, and I -- you have to accept my answers. You know, I'm a medical professional.
Q. Okay. Fair -- I --
It's on the record now that I'm trying really hard to get through this, and if we got to be here all night, we'll be here all night. I've got seven and a half hours with you, so --
Let's go back to my question. When Dr. Daly talked to Noah, he didn't know that the heart that was going to be implanted into Noah's

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chest was coming from a meth addict who had an intracranial hemorrhage; isn't that true?
A. No, he didn't --
Yeah. He didn't know.
Q. The only surgeon who provided informed consent to Noah after that information became available was you; isn't that true?
A. The con --
The informed consent is -- is done previously --
Q. Uh-huh.
A. -- in the surgical note. It's a -- it's a team approach.
Q. Wasn't my question. We'll go back to my question.
The only surgeon who provided informed consent to Noah after the information about the donor became available was you; isn't that true?
A. The surgeon --
Yeah. Uh-huh.
Q. So let's stick specifically with what you told Noah. You told him it was a good donor, --
A. Uh-huh.
Q. -- and then you talked with him about

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the risks and benefits just of the transplant procedure, but not the risks and benefits of the donor organ. Do I have that right?

A. No.

Q. What part do I have wrong?

A. Because how the transplant procedure could be separated from the donor procedure.

Q. Okay. Then tell me with as much specificity as you can what you told Noah about the potential risks of this specific donor organ.

A. I -- I thought it -- and -- it was an --

That it was an excellent donor and that normally -- I can't recall exactly what -- what was the conversation, as I said before -- but, you know, the -- the risk of cardiac surgery, you know, was done. Risks of cardiac surgery are stroke, bleeding, wound infection, renal failure, the whole medicine is a risk. That's the risk.

Q. None of that answered my question at all. I asked you what specifically did you tell Noah about the risks of this specific donor organ.

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A. Again -- again, I already told you that we don't talk in specifics because that's banned, --

Q. So --

A. -- is -- is confidential information about the donor.

Q. So what you told him was this was an excellent donor and that's it.

A. Yeah. And if they had any question -- and I don't recall what other question they have, but I remember that I stayed there answering question for half an hour.

Q. Okay. Let's, again, stick just with the donor organ. Am I correct that the only information you gave Noah Leopold about this donor organ was it's coming from an excellent donor?

A. I don't recall the -- the conversation entirely. I know that the donor told her -- I mean that our transplant coordinator told her that it was from increased-risk donor, and he accepted that.

Q. I'm not talking about what the transplant coordinator talked with him about. I'm not talking about what anybody else talked with him about. We're sticking with you. So --

A. Yeah. That's what --

Q. Hold on. Hold on.

A. But let -- but let me -- you -- you are --

MR. BRANTINGHAM: Wait for --

A. You allude to me, so I need to answer.

Because we are part of the team that informs things to the -- to the -- to the recipient, so I rely in my colleagues, my cardiology, my transplant coordinator to give the most information that we can to the patient. And I went there and spent a half an hour at least talking to them and doing the best job that we can.

Q. Great. Now I've talked to Dr. Rosenbaum and I'll probably talk to the transplant coordinator. What I'm interested in right now, though, is talking to you about what you told Mr. Leopold, so I'm going to go back to my question.

When you spent that half hour talking to Noah Leopold, did you tell him anything about the risks of this donor organ other than just saying "This is an excellent donor?"

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A. I don't recall, but I --

I don't recall any more than that, but it was an excellent donor and continues to be.

Q. Would it be your standard practice to tell a person like Noah anything about the risks of the donor organ other than "You know what, this is an excellent donor?"

A. Well the standard practice is we have to talk about DCD, if it's DCD or not DCD. This donor was not DCD, it was brain dead. Whether or not, you know, it's increased risk, all right, it's already done by the transplant coordinator and we have to -- and -- and if he was hepatitis C or not hepatitis C. This donor was not hepatitic C positive, so that's -- that's why, you know, we have to make sure that we provide that information, and we did.

Q. Okay. Back to my question.

Would it have been your standard practice --

I know you don't remember this conversation, but you know this wasn't a DCD donor; right?

A. (Witness nodding.)

Q. Yes? You've got to say yes for the

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record.
A. Yeah, it was not.
Q. And you know that this wasn't a --
A. And I already told you that already, --
Q. You know this --
A. -- so it's already on the transcript.
Q. You know that this wasn't a hepatitis C donor; right?
A. Yes.
Q. So let's stick with this donor, not some other hypothetical donor. Let's stick with this donor.
A. Well I stick to this donor because, you know, as I said --
MR. BRANTINGHAM: Let him get to the next question, doctor.
A. Yeah. But you are -- you are repeating the information.
Q. Are you ready for me to ask a question?
A. Yes, sir. Go ahead.
Q. With respect to this specific donor, in your general practice, the way that you typically do things, would you have told Noah anything about the donor organ other than it's coming from an excellent donor?

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A. I have to respond again? The only thing that I would have told him about, DCD, hepatitis C, and increased-risk donor, and whether it was something controversial or not. There wasn't any controversial in the donor.
Q. So again, like let's not talk about some hypothetical donor that this wasn't. You told --
A. No, I -- I tell you.
Q. Okay. We're going to keep at this until we get straightforward answers to my straightforward questions. We're going to go back again.
With respect to this specific donor, if you were following your standard practice, would you have told Noah anything about the donor organ other than it's coming from an excellent donor?
A. Well in -- in this case, I wouldn't have told anything because all the evidence was excellent.
Q. Let's talk about the surgery itself.
MR. BRANTINGHAM: We're about an hour in. Maybe take five?
MR. THOMPSON: Sure.

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THE REPORTER: Okay. Off the record.
(Recess taken from 2:16 p.m. to 2:21 p.m.)
THE VIDEOGRAPHER: We're on video.
THE REPORTER: We're on the record.
BY MR. THOMPSON:
Q. Did you look at your operative report as part of preparing to give your deposition today, doctor?
A. Yes, sir.
Q. When is the last time you looked at your operative report?
A. This morning.
Q. All right. Do you remember which of the two procurement surgeons called you to talk with you about the assessment of the heart when they were still in Idaho?
A. I don't.
Q. Do you know for a fact that one of them called you?
A. I don't. I don't know. I trust both.
Q. When you say you trust them, you trust their assessment?
A. Yes.
Q. Do you feel confident that they can

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independently decide that a heart is suitable for transplantation?
A. That's the normal clinical practice all over the world.
Q. Is the normal clinical practice at Mayo for them to call you and walk you through what they're seeing, or is it for them to just make the decision that this looks good?
A. No, it's mandatory a phone call.
Q. Okay. How long does the phone call usually last?
A. Five minutes.
Q. What sorts of information do they generally provide you?
A. If there's any contraindication in the donor; for example, if they see a tumor, for example. They want to see how the function of the heart, what are the hemodynamics, if -- if they palpate any coronary disease, verify everything that is in the computer, you know, in the computer -- in the donor that -- there's some information, but you have to verify it onsite. That's the normal way.
[redacted]

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[redacted]

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[redacted]

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[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. Did you review the donor's health summary?

A. Yes.

Q. From UNet?

A. Yes.

Q. When?

A. I -- I don't know if the offer was done the night before or during the day. I can't remember exactly.

Q. How much time would you generally spend going through the UNOS records that are made available to you?

A. Around a half an hour.

Q. Do you remember if there were other hearts that were offered to Noah that day that were just as suitable for him?

A. No. There wasn't any.

[redacted]

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[redacted]

Q. Okay. How long do you think Noah could have waited to get a heart?

A. It's -- it's --

You can't predict that. He could have died next day.

Q. Do you think he probably would have died the next day if you --

A. Could have happened. I've seen it many times.

Q. Well he survived for a week even after you took his heart out and left him without a heart; right?

A. Yeah, because I implanted acute circulatory support on him.

Q. Sure. Weren't --

Wouldn't there have been lots of intermediate steps to help Noah's circulatory function if he had continued to go downhill in the week or two after the 29th if he had chosen to wait?

A. If he had chosen to work, let's suppose that you need to do more, that will, you know,

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worsen his prognosis.

Q. Do you know that the other doctors who have testified in this case have said Noah could have survived weeks or months?

A. I don't agree with that.

MR. BRANTINGHAM: Foundation.

Q. Okay.

MR. BRANTINGHAM: Yeah.

A. I don't agree with that and -- because he was in cardiogenic shock. He had a right heart catheterization show extremely low cardiac index, so he could have died next day. Moreover, he got end-organ dysfunction several days before. So there was evidence of, you know, kidney dysfunction and liver dysfunction, so you don't want your patient to suffer more organ dysfunction before transplant.

Q. So if he was in such dire straights, do you know why Dr. Daly didn't transplant him in the week before you came on the service?

A. I --

The only thing that I recall -- I don't recall -- recall anything about Dr. Daly. I recall Dr. Spencer, that he got an offer, and he has an increasing in his creatinine, so

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end-organ dysfunction what I'm telling you, and so they -- they elected to wait until the kidney function, you know, could have gotten better, signs that he was very sick and in cardiogenic shock.

Q. And it did get better in less than 24 hours; didn't it?

A. I can't recall how were the measurement of the kidney function, but normally that happens over two or three days that it get better, the kidney function. But he didn't have normal kidney function for sure.

Q. If Noah's kidney function improved over the course of less than 24 hours, that would be a good sign for him; wouldn't it?

A. Yeah. But it would be a good sign in terms of, you know, he had some recovery with the circulatory support, but what it tell us that he's in a very borderline situation.

Q. Would you have preferred for Noah to have had a combined heart-liver transplant?

A. No.

Q. Why not?

A. Because a heart-liver transplant carries a mortality between 30 to 50 percent.

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Heart transplant might be two to three percent. Comparative mortalities that we're talking.

Q. Have you seen the email exchanges where Dr. Spencer and the rest of the team were actually pushing for him to get a combined heart-liver transplant?

A. I -- I don't remember seeing those. I -- I know that the liver team, which are the experts, said that he didn't need a liver transplant.

Q. Do you remember when you gave that presentation with Dr. Friedman talking about the advantages of doing a combined heart-liver transplant?

A. Yeah. That has some advantages related to the antibodies that have been published here at Mayo.

Q. One of the other advantages is that you avoid coagulopathy; right?

A. Well that -- that, in terms of if you implant the liver and it works fine, it might, you know, get the -- the coagulation better, but certainly not normal, because when you do a heart-liver transplant there is a huge derangement on the coagulation factors. So if

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you ask me what has more coagulopathy, certainly a heart-liver, but within the heart-livers, doing the liver first would have less coagulopathy.

Q. And as you said in your interview with Dr. Friedman, "there's less coagulopathy, so the liver is working" and "patients bleed less," and that's quite an advantage. That's right; right?

A. It has not been demonstrated extensively, but it's a physiologic thought.

Q. Do you think that Noah's liver dysfunction had anything to do with the bleeding event you experienced in the operating room?

A. No, I don't think so.

Q. Why is that?

A. Because we, you know, rely on the assessment of the expert, the liver transplant people, that his synthetic function was good before the transplant, and that includes the coagulation, so -- and as a doctor, what I can see, his coagulation was good and -- but -- and so I don't think it has nothing to do.

Q. If his coagulation good -- was good, why were you unable to get the bleeding from his heart to stop?

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A. Well because it was bleeding diffusely, you know. It's for me just a theory -- I don't know what it was bleeding. It's first time I have seen this, so it was bleeding from all over the heart, so my suspicion there was, you know, microtears on the aortic root and that infiltrated the heart and make it bleed from everywhere. It's a hypothesis. I don't know really what it -- why it bled from everywhere.

Q. That hypothesis that you just described about there being microtears from the aortic root, --

A. Uh-huh.

Q. -- that's the best hypothesis you can come up with based on your years of education, --

A. Uh-huh.

Q. -- training, and experience and the fact that you were the one who was actually there watching it bleed; right?

A. Yep. Yes, sir.

Q. Where would those microscopic tears have come from?

A. Because the OCS, you know, perfuses blood on the aorta. So if you perfuse on the

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aorta blood, you know, that, you know, might cause a tear on the aorta, you know. So, as I said, we normally see a little -- little bruising, and in this case we saw a little bruising also. But, you know, that progressed, you know, after the heart was transplanted, I -- and causing the significant bleeding.

Q. Where was the bruising that you saw when the heart came out of the OCS machine?

A. Normally there's a little bit in the -- in the fat that is around the aortic root.

Q. And that's where it was in this case?

A. Yeah.

Q. What percentage of hearts that come off the OCS have bruising that looks like that?

A. Ninety percent.

Q. Ninety?

A. Well I mean I haven't done the statistics, but like educated guess.

Q. In your experience.

A. Yes. Ninety percent.

Q. You described the heart as being large when you retrieved it from the OCS device. Was it large as in it was edematous?

A. No, it was large in size. The -- the

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heart didn't have hypertrophy as was demonstrated by the echocardiogram on the donor. There was no hypertrophy. It was just large in size.

Q. Is it part of your usual practice to do a predicted heart mass calculation prior to transplant?

A. Not usually.

Q. Why not?

A. Because we would rely on other factors, the height, the weight, the gender of the donor, the gender of the recipient. And, for example, the -- the donor hearts that are 70 kilograms or higher in weight, they usually will be adequate for all recipients in terms of hemodynamic performance. And then you have to assess if the heart will fit in the chest, so we normally do measurements on the CT scan on the donor, and measurements on the CT scan on the recipient to see if the heart will fit.

Q. And you were fine --

A. But the -- but the ultimate test is putting it in.

Q. Sure. And in this case you had to make some adjustments in order to get it to fit.

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A. Yep.
Q. All right. The beginning of your operative report you say, "Once I gave word that the donor heart was suitable for transplantation, the patient was anesthetized." Would that have been after you got the call from the procurement team in Idaho?
A. Yeah. Not --
Well in heart transplantation, there's minimum morbidity of putting somebody under general anesthesia, so it depends a little bit on the situation. In his case, I waited for the heart to be on the -- I can't recall exactly, but most of the time I would wait for the word that it's fine, and then if it's fine, then general anesthesia allowing some prepping and draping. And then we try to match the -- when the heart arrives when the -- with the explantation.
Q. Sure. So make sure I've got this right. Anesthetized probably shortly after you got the call from Idaho --
A. Uh-huh.
Q. -- that we've evaluated the heart, it looks good.

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A. Okay. Yeah, likely. I can't recall ex -- what was the timing exactly, but that's the most common thing. In a patient like Mr. Noah, because he -- you know, sometimes you need more time because the -- this -- you anticipate a complicated operation, so you would anesthetize earlier than that.
Q. Noah had what's known as a virgin chest; right?
A. Yeah, he did.
Q. I assume that you had no problems whatsoever accessing his native heart and explanting it?
A. Yeah. I had no problems that I remember.
Q. How long did it take?
A. It would take around, to explanted it --
Well one thing is the explantation, one -- a different thing is the -- you know, open it up. So if you -- if you count from the skin incision to get the heart out, an hour, an hour and a half.
Q. When -- when would you have made the skin incision?

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A. The -- the skin incision, we would do it -- we anticipate the -- the estimated time of arrival. So, you know, if it take me an hour, an hour and a half, you know, to open, cannulate, take me an hour and a half, so we -- when the airplane is usually on the air, then we see what is the estimated time of arrival and try to match it the best we can.
Q. I understand.
So the goal, in terms of timing, would be you've made the incision, you've done -- you've cracked the chest, you've got everything cannulated, you are basically ready to remove the heart when you get the call from the ground in Rochester that they've landed safely.
A. It depends, again, on what's the complexity. In his case, I mean we don't crack the chest, we do a midline sternotomy.
Q. Okay.
A. And so most of the time, if it's a virgin chest, we'll be with the chest open and cannulated, so when they land and they tell us that the heart is fine, then it will go bypass and take the heart out.
Q. Got it.

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Fair to say you don't remember for sure if that's what you did in this case, but based on your general practice you think that's probably what happened.
A. Yeah.
Q. Describe for me --
You write in your operative note about adjusting the sutures, opening the posterior and left-side pericardium to make this larger heart fit.
A. Uh-huh.
Q. Describe what you're talking about there.
A. So the -- the pericardium is the linings -- the lining of the heart. So if you open it in the back and to the left, you get an opening to the left chest so there's more room. So that's what I did, I opened -- so I give more room to the heart. And then the adjusting of the sutures meaning, you know, what we call compensating. When we do the suture, we take more in one side than the other side. So if you sort of -- if you take -- so you have something big and something small, you will take normal bites in the bigger one while you will take very

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close bites on the smaller one.
Q. Okay. So obviously this was different because you ended up having to take the heart out. But if things had gone the way you wanted them to, would the pericardium have been completely stitched closed at the end of the operation?
A. No, I don't do that.
Q. Because of swelling?
A. No. I -- I don't like to close the pericardium, because if you have a closed cavity there's always some oozing of blood, so you could have accumulation of clots and blood and have, you know, tamponade.
Q. Tamponade.
And so the pericardium would just be left partially open permanently?
A. Yes. So I, in all the cases, I leave -- open it permanently on the front.
Q. On the front.
A. In this case it was additional on the back to the left.
Q. Because the heart was bigger than --
A. Yes.
Q. Okay. All right. Everything went

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according to plan until the cross-clamp was removed. Am I correct about that?
A. Yes.
Q. Describe for us then what happened once you took off the cross-clamp.
A. So the -- the heart start becoming more bruised overall until it start bleeding from several spots. And we normally handle the heart to check, you know, for bleeding in the back and the front. So all those, when we grabbed, that -- so we grabbed the heart, and then that kind of broke off the epicardium, you know, the layers or bled through there, and then that process continue.
Q. Was the blood infiltration spreading from that location of ecchymosis near the aortic root?
A. I don't know because it was all over the place, so I don't know.
Q. It was all over the place by the time you noticed it.
A. Yeah.
Q. Okay. All right. Estimate of how many different places it looked like it was bleeding from when you first noticed it.

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A. You cannot quantify because it's diffuse bleeding, so you can't count it.
Q. All right. At what point in the process did you begin to suspect that it was these microscopic tears?
A. When -- when there was bleeding from all over the place, so I -- I -- I suspect that that could have been the case.
Q. Okay. What did you do about it?
A. I -- I --
You know, you are fully anticoagulated when you are in that situation because you on the heart-lung bypass machine, you need to do that fully anticoagulated, so I -- I came off -- off the heart-and-lung bypass machine and I gave protamine. We tried to seal those suspected microscopic holes.
Q. And that didn't work.
A. No, it didn't. And actually the heart, it squeeze quite well, had normal function at the beginning. But as it get more and more infiltrated, the function, you know, went down.
Q. Okay. Were you -- your assistant was --
You had one assistant. It was a

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fellow; right?
A. Yeah.
Q. Did you, during this time, did you contact either Dr. Daly or Dr. Spencer?
A. No, I didn't.
Q. All right. How long did you spend trying to get the bleeding under control?
A. Several hours.
Q. Do you think that there may have been a component of DIC involved here?
A. I -- I haven't heard about any labs confirming or denying that. Nobody told me anything about that.
Q. Well after the fact I presume that you were racking your brain and looking at the data and trying to figure out what happened here to cause this thing that I've never seen.
A. Yeah. But, you know, I -- I'm hands on, you know, trying to get the patient to stop bleeding, so normally the -- the anesthesiologist will be looking at all the coagulation tests, and if there's anything abnormal, they try to correct it the best they can.
Q. And the anesthesiologist didn't say

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anything to you about there being a coagulopathy.

A. Well I, you know, I knew that he had coagulopathy because the way, you know, it was bleeding all the time. So he had coagulopathy as 90 percent of the heart transplant we do, they have coagulopathy.

Q. Yep.

A. So -- so we gave --

We usually do two things. We'll give blood products and we give concentrated blood products, meaning like a powder of, you know, clotting factors that is, you know, injected intravenously. So that was tried. It was tried when we give the protamine and it was tried again. You know, then I, you know, had to go on the heart-and-lung bypass machine and then I went on -- on ECMO to give more support to the heart. And then we gave more products, more concentrated of blood products, and the bleeding would not subside.

Q. And then eventually you decided the only thing left to do is take this heart out.

A. Yes.

Q. Is that the first time that you have

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left a patient without a heart?

A. No. The -- there was a colleague of mine that had a bleeding -- it's called an atrioventricular dysjunction, you know, the atrium and the ventricle, they separated, and then you try to put it back together. And then we tried everything for that and it didn't work, so we took the heart out, the patient stopped bleeding.

Q. Tell me about this attempt to put in a BiVAD oxygenator implant.

A. Uh-huh.

Q. First of all, what is it?

A. So it is essentially cannulas to drain the blood. We put one cannula here on the right femoral vein, another one here, so trying to re-create the normal circulatory system. So cannulas drain the blood from the veins, then inject them from the pulmonary artery, then coming back from the pulmonary veins, and then drain it to another pump, and then that's going into the outer, to the rest of the body. That's -- and then you inter -- in one of those circuits or those pumps you'll interpose an oxygenator to oxygenate the patient, so provide

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circulatory and gas-exchange support.

Q. How does that setup differ from ECMO?

A. It's just in -- in ECMO you have the -- the heart is still in. So you have the can -- cannula, you know, on the right femoral vein and another one here in the artery here or here. Actually we had that for a little while.

Q. Yep.

A. And that's the difference, in one there's heart, in the other one there's no heart.

Q. Okay. So this BiVAD setup, the BiVAD is basically taking the place of the heart.

A. Yes.

Q. Because without either a donated heart or the explanted native heart, there was nothing for things to flow through without putting in the BiVAD?

A. Yeah. Because it, you know, it was bleeding all over the place so, you know, my alternatives was let the patient die on the table or attempt a BiVAD oxygenator.

Q. After the surgery was finished, did you talk with Noah's family?

A. I remember talking multiple times to

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them.

Q. Tell me what you remember.

A. Essentially the description that I gave you, that the heart, after we took the cross-clamp out, got an extensive hematoma, started bleeding from everywhere. We tried to fix it with all these maneuvers that I have just told you. The same story.

Q. Did you tell them that you suspected that it was -- the cause of this was related to the perfusion on the OCS machine?

A. Yeah, yeah. I -- I told them that. Because they tell me, "Why -- why -- why that would happen?" I said, "I suspect that there might be micro -- microholes, you know, that caused this."

Q. How would the holes have been created, with the pressure from the perfusion?

A. With the pressure of the perfusion.

Q. So this is something that's never been reported anywhere else in the world; true?

A. I -- I have not seen it myself before.

Q. Have you heard of it?

A. No.

Q. If it was the pressure from the OCS

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machine that caused these little microholes in the aortic root, why would that have never happened before?

A. May -- maybe the --

You know, you don't know what the resistance of the tissues of each person. Each person is different, so maybe this one has less resistance.

Q. Yeah. That's kind of where I was going with it. It sounds like -- it sounds like whatever the problem was, it was something wrong with that heart; right?

MR. BRANTINGHAM: Foundation. Go ahead.

A. That -- that could not be stated with our current methods of diagnosis.

Q. Your best explanation is that there was something wrong with the heart.

MR. BRANTINGHAM: Same objection. Go ahead.

A. Well after the fact.

Q. Sure. No. Absolutely.

A. In hindsight.

Q. Does this event give you any concern about the use of OCS for other donor hearts?

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A. Well it gives me a concern, of course. You know, we remember our bad experiences, so --

Q. I'm talking about, though, specifically with respect to OCS. So the best explanation you've been able to come up with this is that there was something about the pressure on the OCS machine perfusing the aortic root that caused little microperforations that led to this disastrous --

A. Yeah.

Q. -- transplant attempt. Does that give you pause in using the OCS in the future?

A. Well but I have to see the bulk of my experience with OCS. So I have been able to transplant successfully many, many patients with the OCS. So it's important not to be guided emotionally, but be guided scientifically and see if it would happen ever again.

Q. Now there have been a number of studies, and there are ongoing studies, about the OCS; true?

A. (Witness nodding.)

Q. Yes? You got to --

A. Yes.

Q. -- say yes.

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Have you written or are you intending to write a case report or anything else about this case?

A. Well there has been at least two doctors in training at the Mayo Clinic that have wanted to report this case. And I suspected it could have legal implications, so I told them to wait.

Q. Help me understand that, please.

A. You know, because, you know, if, you know, the -- the family, you know, would, you know, make a claim against us, you know, we don't want to, you know, publish it in the newspaper.

Q. So the reason that one would put out a case report about this is so that other doctors can be aware that this happened and let's try to figure out how we can try to prevent it from happening again; right?

A. Yep. But I would let the dust settle so there's no emotional decisions taken.

Q. No, no. Let's stick with my question though.

The reason that stuff gets published in the medical literature is so that the medical

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community can benefit from sort of the high of mind; right?

A. That's one of the benefits.

Q. Right.

And specifically, with respect to this incident, it could have implications for the OCS if your hypothesis is true; right?

A. Yeah.

Q. And some of your colleagues want to write a case report about this case to put it out there into the medical literature to get other people thinking about it in order to advance science and patient safety; right?

A. Yeah. We likely will.

Q. But you're telling me that Mayo has elected not to do that --

A. No. I told them not to do it yet.

Q. Okay. You told them not to do it yet because you're worried that there may be legal ramifications.

A. Yes.

Q. And legal ramifications are you don't want there to be a case report that's going to be out there in the newspaper.

A. Well I -- I don't want bad publicity

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certainly.
Q. Why not?
A. Because that will affect Mayo and other patients -- will affect other patients mainly. They would, you know, not receive the care that they need.
Q. So you're withholding potentially important scientific information in order to avoid bad -- bad publicity for Mayo.
A. No, sir.
Q. Okay. Have you reported this to TransMedics?
A. No.
Q. Why not?
A. Because we wanted the dust settled before tell other people.
Q. How long are you waiting for the dust to settle?
A. Until we're finished with your claim.
Q. Okay. So hold on. Your best hypothesis is that there was something about this OCS machine's perfusion that caused a catastrophic loss of this donor heart. Yes? That's your best hypothesis.
A. Yes.

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Q. You certainly know that TransMedics would like to know about this.
A. They already know.
Q. How?
A. Because you already reached to them.
Q. Right. I reached to them to get medical records.
How do you know that, by the way?
A. They -- they told me. You know, I was told that -- that -- I don't remember who it was that told me that you were asking about the -- the records.
Q. Oh, somebody at TransMedics?
A. Yeah, likely.
Q. Got it.
A. Filtrated.
Q. So I called to get --
I contacted TransMedics to get records, and TransMedics called you and said --
A. No.
Q. -- "Hey, just so you know, some lawyer's poking around."
MR. BRANTINGHAM: Object to the form of the question.
A. No.

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MR. BRANTINGHAM: Go ahead, you can answer.
Q. Okay. So what am I missing? Tell me about this conversation.
A. No. There's -- there's -- there's, you know, the International Society of Heart and Lung Transplantation meeting, and then we see all the people there, you know, including -- including the TransMedics people because they present their technology, so they told me there was a lawyer looking for the records.
Q. Who told you?
A. I don't remember.
Q. Somebody from TransMedics.
A. Yeah.
Q. And it was while you were at the International Heart/Lung Transplantation Society meeting?
A. Yes.
Q. Where?
A. In Prague.
Q. In Prague?
When?
A. In April.
Q. Have you talked to anybody else about

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this?
A. No.
Q. Nobody?
A. I think I told my -- my chairman. I think I -- for some reason I had to tell my chairman, I don't know why, and the director of the transplant center here, but other than that.
Q. Have you talked with any of the people who are currently doing research on the OCS?
A. Like who?
Q. Well any of your colleagues, people at Duke or people at Mass General or people anywhere else?
A. No. No. I was requested not to talk to anybody. And I didn't ask this TransMedics thing that I was told. They told me. I didn't ask in the IHLT meeting. They told me that, so I didn't ask. And so I haven't wanted to talk to anybody --
Q. Okay.
A. -- about it.
Q. So the people from TransMedics told you there's a lawyer asking questions.
A. Yeah.
Q. Did you tell them anything more about

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the case?
A. No.
Q. Did you just -- you say, "I've been advised to not talk about it?"
A. I -- I said "Okay" and I walk away.
Q. You said o --
A. "Okay" --
Q. And walked away.
A. And then I walk away.
Q. Did the person from TransMedics think it was strange that you just said "Okay" and walked away?
MR. BRANTINGHAM: Foundation.
Q. Did they seem like they thought it was strange?
A. No, no, because you have very short conversations normally in these meetings. You talk to somebody and go, talk to somebody and go. It's normal. I don't want to be rude with people, so I -- I don't tell them, you know, "Shut up," you know. I don't -- you know, I don't want to talk to anybody about it. So I was told, I said "Okay," I walk away.
Q. Why haven't you talked with any of your cardiac transplant surgery colleagues about this

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case outside of Mayo?
A. In other -- in other centers you mean?
Q. Outside of Mayo.
A. Because I was recommended not to talk to anybody about the case. I think this was in February. I believe so.
MR. BRANTINGHAM: Well don't get into our communications, doctor, but your best memory in response to Mr. Thompson's questions is all you can give him.
A. I --
MR. BRANTINGHAM: Let's have another question because I'm unsure even what the question is right now.
Q. Did you report this to the FDA?
A. No, I haven't reported it to FDA.
Q. Why not?
A. Because, you know, I was told to not talk to anybody, --
Q. Well --
A. -- legal matters.
Q. Right. But there were no --
There was no legal issue in September of 2023; right? Right?
THE REPORTER: Your answer?

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Q. You got to answer my question.
A. Yeah. There wasn't, but I suspected there could have been.
Q. You suspected that maybe there was going to be a claim as far back as September of 2023?
A. Yes.
Q. And so you made the independent decision that, "Well, because I think there may be the possibility of a legal claim, I'm keeping this under wraps and I'm not telling anybody."
MR. BRANTINGHAM: Object to the form of the question.
A. Yeah. I -- I prefer not to talk to -- again until, you know, I'm sure that there was not going to be any claim.
Q. And then October passed and November passed and December passed and you didn't hear anything about a claim; right?
A. No, I think I heard it in February.
Q. No. So we'll get to that.
September, October, November, December, four months you heard nothing about a claim and you still kept it under wraps, didn't report it to the FDA, didn't talk to TransMedics about it,

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didn't talk to anybody outside the little Mayo cocoon.
MR. BRANTINGHAM: Object to the form of the question. Go ahead.
A. Yes. I believe that's a short time in clinical terms.
Q. Okay. Did you think about reporting it?
A. Well, yeah, after I'm sure that there's no legal claim.
Q. Who are your colleagues here who want to write a case report about it?
A. The transplant fellow, I believe, and other one I think it was a cardiology fellow -- no, no -- an intensivist fellow, but I don't even know his name. I mean I know the name of the cardiac fellow.
Q. When did they tell you that they want to write a case report about this?
A. I don't remember.
Q. Before February?
A. I don't --
I suspect December, January, I suspect. I can't -- can't recall.
Q. And you told them "Let's just kind of

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wait for the dust to settle and see if there's a legal claim."

A. Yes.

Q. Do you know that there is a Patient Safety Incident Reporting Guideline at Mayo?

A. No, I don't.

Q. Do you know that there is an online incident reporting tool available to the transplant team at Mayo?

A. No. I -- I -- I suspect that there could be something to report, but -- but -- but I -- I haven't used it ever, so I don't know.

Q. Do you know what the MAUDE database is?

A. No.

Q. Do you know that the FDA maintains a database that allows doctors to report incidents with medical devices so that it can raise awareness throughout the medical community?

A. It would have been already published if it wouldn't been a claim, and then everybody will be ed -- it would have been educated. But because there was a claim, there's no education.

Q. None of that was my question. I'm going to go back to my question.

A. It is -- it is my answer.

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MR. BRANTINGHAM: Wait for the question, doctor.

Q. Are you familiar with the fact that the FDA has a publically-accessible database that allows doctors to report problems with devices?

A. No, I'm not aware. What is the particular database? I suspect that there's a reporting instrument, but I -- I don't know the specifics.

Q. Would you like to report this catastrophe to somebody outside of Mayo?

MR. BRANTINGHAM: Object to the form.

A. I -- I would like to publish the case and at the same time report it to the FDA.

Q. And you're planning to do that, but just you're going to wait until this lawsuit's over.

A. Yes.

Q. Because you don't want there to be bad publicity for your transplant program.

MR. BRANTINGHAM: Object to the form of the question. Go ahead.

A. Because I -- I have been advised not to talk to anybody by my legal team.

MR. BRANTINGHAM: And -- and just

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ensure you don't talk about our communications, doctor, or --

THE WITNESS: Okay.

MR. BRANTINGHAM: -- the communications with Mayo Legal.

Q. But I think you told me before that one of the reasons why you didn't talk about it, even before the legal team got involved, was because you didn't want bad publicity for the transplant program.

A. Yeah, I think that's accurate.

MR. THOMPSON: Let's take a break.

THE REPORTER: Off the record.

(Recess taken from 3:11 p.m. to 3:35 p.m.)

THE VIDEOGRAPHER: We're on video.

THE REPORTER: We're on the record.

MR. BRANTINGHAM: Before you proceed, I -- pursuant to the protective order, I want to designate this transcript as confidential.

MR. THOMPSON: All right. Based on?

MR. BRANTINGHAM: Based on all of the PHI, all of the sensitive health information in it, based on the totality of everything we're talking about.

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MR. THOMPSON: Okay.

BY MR. THOMPSON:

Q. All right. Doctor, despite this event that you're planning to someday report to the FDA and TransMedics, Mayo is continuing full bore using the OCS; right?

A. Yes.

MR. BRANTINGHAM: Object to the form of the question. Go ahead, doctor.

A. Yes, we are using OCS for heart transplantation.

Q. You haven't reduced your use of OCS since this event; have you?

A. No, I have not.

Q. You've increased your use of OCS.

A. No. I haven't done the statistics, but it looks like around the same.

Q. When you went to Prague for that International Society meeting, you presented on TransMedics data; right?

A. Yes.

Q. Did TransMedics provide you a stipend?

A. No.

Q. They didn't cover any of your travel expenses, nothing.

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A. No.
Q. All right. You presented on --
Part of what you presented on was information about TransMedics NOP program; right?
A. OP?
Q. NOP? Their National --
A. Oh, the National Organ --
Q. National OCS Program.
A. Not -- not quite the same.
Q. Okay. Let me ask it a different way.
You know about TransMedics' National OCS Program; right?
A. Yeah. I have not used it.
Q. No, I know. But you know what it is?
A. Yes.
Q. What it is?
A. Which is that the transplant procurement surgeons from TransMedics will go and fly out and retrieve an organ on the OCS to the transplant center to get transplanted.
Q. TransMedics has their own planes; right?
A. Yes.
Q. They've got dedicated people whose only

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job is to do organ procurement for OCS transport; right?
A. Yes.
Q. Why doesn't Mayo use that service?
A. Be --
There's two reasons. Because one thing, it's more expensive, so I want to, you know, be as inexpensive as possible. And the second reason is they are -- the surgeons are, you know, TransMedics' employees, so I see a conflict of interest. So I prefer my own people to assess the organs and put them on the device if needed.
Q. Doesn't it make sense to you to have the most experienced people possible running this complicated machine?
A. Yes, but with no conflict of interest.
Q. How is it a conflict of interest to have the most experienced people operating a machine that they know better than anyone?
A. Yeah. Because their salary depend on the company, so I want people with no salary from the company.
Q. How does that --
You got to help me understand that.

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Wouldn't outcomes be better, presum --
Well let me ask you this question: Do you agree with the basic concept in medicine that the more experienced you are, in general, the better you are at doing things?
A. Yes.
Q. One of the reasons why you're trying to bulk up the transplant numbers in the Mayo heart transplant program; right?
A. Yes.
Q. So wouldn't it stand to reason that if you've got OCS specialists who literally all they are doing day in and day out is doing OCS organ procurement, that would lead to improved clinical outcomes?
A. No, sir.
MR. BRANTINGHAM: Foundation.
A. That's wrong.
Q. Are you familiar with TransMedics' statistics on clinical outcomes for facilities that are using their people as opposed to using other people?
A. No, I don't.
Q. You haven't even bothered to review their statistics as part of deciding whether

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you're going to use their TransMedics program?
A. I don't see -- I --
I don't know where are the -- the centers that, you know, doing their own at this point in time.
Q. Now your hypothesized problem with this heart was that there was something about the way that the blood was being perfused into the aortic root through the OCS system; right?
A. No, not -- not in the way. I -- I suspect that, you know, all the hemodynamics parameters are good, so I suspect there is something in -- in the tissue of the -- the heart that cannot be assessed with the current diagnostic methods that, you know, made them weakened to filtrate the blood.
Q. Got it. That this heart that came from the meth addict, intracranial hemorrhage, alcoholic, cigarette smoker, convicted felon with all those drugs in his system, maybe there was something wrong with his heart.
MR. BRANTINGHAM: I'll object to the form of the question. If you can an -- go ahead if you're --
A. Well looking -- looking back, because

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there were this bleeding and you could think that there's -- there was something wrong with the heart, but with all the diagnostic tools that we currently have, the -- the heart was excellent.

Q. Well you thought the heart was excellent, but now we know, in retrospect, your best hypothesis is there was something wrong with that heart; right?

A. The --

No. No. The heart was excellent by the, you know, criteria of the International Society of Heart and Lung Transplantation, you know, published last year. It checked all the boxes for an optimal, excellent heart.

Q. Wasn't my question though.

Your best hypothesis is there was something with the tissue in that particular heart that made it not able to withstand the perfusion pressures on the OCS machine like every other heart you've ever had on the OCS machine did; right?

A. Yes, but I couldn't diagnose that.

Q. I know you couldn't diagnose that. But your best hypothesis is there was something

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wrong with that heart; right?

A. Yep.

MR. BRANTINGHAM: Object to the form. Go ahead.

A. Something that was microscopic and not see it with the current diagnosis test again.

Q. Well your people didn't see it. We don't know if maybe the more experienced TransMedics people wouldn't have seen it; do we?

MR. BRANTINGHAM: Foundation.

A. That's very unlikely.

Q. Why?

A. Because my people are -- are trained and they work in an academic surgical center. TransMedics is not -- doesn't have a Department of Cardiovascular Surgery. So you would think that you would like to have heart surgery, you would go to the Department of Cardiovascular Surgery, not to a company.

Q. Do you know how many OCS procurements the TransMedics NOP Program have done?

A. I don't.

Q. So you don't know how many orders of magnitude more they've done than your people at Mayo.

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A. Yeah. I don't know.

Q. Do you know how many OCS runs the OCS specialist from Mayo who was responsible for the perfusion on this heart had been on?

A. I don't. I haven't counted.

Q. Would it surprise you to know that she testified yesterday that it was probably something like six or seven at the time she did this run?

A. I think there were two normally. I think there were two perfusionists normally.

Q. Okay.

A. So you have the count. I don't know the count of how many have they gone.

Q. And as for whether the OCS specialists in the NOP Program are orders of magnitude more experienced than the Mayo people, you just don't know.

A. No. I -- I don't know. But -- but again, they have a conflict of interest. So we don't want conflict of interest in the decisions of -- in heart transplantation.

Q. I'm still having a hard time understanding the conflict of interest as it applies to patient outcomes. Are you suggesting

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that because these people are paid by TransMedics, they somehow have an incentive to not do as good of a job?

A. No, they try to do a good job, as any human being likes to do, but their incentive is different. You know, they are not part of the Department of Surgery, so they are not doing surgery all the time. That is a problem. They are just doing procurements. So in any unexpected thing that can happen, it will be more difficult to, you know, handle because they are not in everyday surgery. And then their incentive is to do more hearts or more lungs. They are -- you know, they do not have an incentive for the outcome as I do. I have to respond to the patient and the family --

Q. So you're telling --

A. -- or my institution, et cetera.

Q. So your testimony is that having people going and procuring these organs, who all they do is procure organs rather than actually doing surgery, is a problem.

A. Yes.

Q. You know that Dr. Altarabsheh literally only procures organs; right?

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A. No.
MR. BRANTINGHAM: Object to form.
A. No, no. He doesn't.
Q. That was his testimony under oath.
A. No. He doesn't.
MR. BRANTINGHAM: Hang on. Just hang on. That's not a question.
Q. Are --
Is it your testimony that you think that Dr. Salah Altarabsheh does something else for Mayo other than procure organs?
A. Yes.
Q. Would it surprise you to know that his testimony under oath on Monday was that that literally is all he does for Mayo?
MR. BRANTINGHAM: Object to foundation.
A. Well that would have been wrong because I have seen him in the -- in the OR working.
Q. Doing what?
A. Heart surgery.
Q. What kind of heart surgery?
A. Helping in heart surgery, assisting.
Q. Helping. What does he do when he's helping?
A. Like any doctor helps in surgery, you

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know, goes in front of the primary surgeon and helps expose, hold the stitches, aspirate, so on and so forth.
Q. Okay. I want to get a list of all the things that Dr. Altarabsheh does that makes him more competent than these TransMedics people. He helps with exposure sometimes; right?
A. Yeah.
Q. Okay. He holds stitches. Is that what you said?
A. Yeah. So he's a first assist in surgery.
Q. Yeah. What else have you seen him do?
A. Well he goes to the conferences. There's morbidity and mortality conferences, so he discuss the cases here -- here in the -- in the board reviews, in knowledge-review content, all the academic work that is done at the Mayo Clinic Department of Cardiovascular Surgery.
Q. Yeah. We're going to stick just with skills for now, so --
A. That's a skill, sir.
Q. Technical skills.
A. Those are technical skills.
Q. Attending conferences?

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A. Yes. When you go and discuss a case in a conference, that's a technical skill --
Q. Got it.
A. -- where you have to learn, you know, how to do things and what's the most appropriate treatment.
Q. Let's talk about what he's doing in surgery. I want to make sure I get a complete list of the things that you say you've seen Dr. Altarabsheh do in the operating room at Mayo. You said he helps with exposure, sometimes he holds stitches. What else have you seen him do in the operating room?
A. He helps from the surgery from start to finish, open the chest, close the chest.
Q. That would be helping with exposure; right?
A. Yes.
Q. So let's --
A. That's surgery.
Q. Yeah. No, I know.
A. What -- what else -- what else are you asking about?
Q. I'm -- I'm not a heart surgeon and I'm not the one --

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A. Well --
Q. Just hold on.
MR. BRANTINGHAM: Hang on. Yeah, just --
Q. You asked me a question. Now I'm going to try to provide you information to clarify what I'm trying to get at here.
You're the one who testified that the people in the TransMedics NOP Program aren't as competent as your Mayo people because all they do is procure organs. I pointed out to you that Dr. Altarabsheh testified that all he does is procure organs. And now you're saying that's not true, I've seen him do stuff in the OR.
A. Correct.
Q. So now I'm trying to get a complete list from you of the things that you have seen Dr. Altarabsheh do in a Mayo operating room, and so far we've got he helps with exposure and sometimes he holds stitches. What else does he do in the operating room?
A. Suctions.
MR. BRANTINGHAM: Go ahead.
A. He separates.
Q. Separates what?

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A. The -- the tissues. He does traction, countertraction.
Q. Is there --
A. All -- all the scope of heart surgery.
Q. Is there anything that Dr. Altarabsheh does that you wouldn't let a second-year resident do?
A. No, he can do way more than that.
Q. Well you let second-year residents help with exposure; right?
A. No, sir.
Q. No?
A. No.
Q. Okay. How experienced does somebody have to be in their training before you'll let them help with exposure?
A. They usually a PGY-7, -8, or -9, so seven years, eight years, or nine years of training.
Q. Got it. Got to be in the seventh year of your residency.
How about holding stitches?
A. Holding stitches, it could be even complicated for a heart surgeon to hold properly a stitch.

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Q. Okay. How far does somebody have to be in their training in the Mayo program before you'll let them hold stitches?
A. In the Mayo program?
Q. Well you teach Mayo doctors; right?
A. Well I teach Mayo -- Mayo doctors, but they already have learned in general surgery how to hold the stitches in simple operations. In complicated operations, I tell them how to do it.
Q. Understood.
A. But it's not the only background that Dr. Salah Altarabsheh has.
Q. Okay. Providing suction. How experienced does a doctor have to be to provide suction?
A. Very experienced.
Q. Very experienced?
A. Yes.
Q. How experienced?
A. In heart surgery.
Q. How experienced?
A. Years. More than ten years of heart surgery.
Q. More than 10 years out of

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their residency?
A. In being in heart surgery in general, residency, residency practice.
Q. Before they can provide suction.
A. Yes. If you do suction in an appendectomy then, you know, an intern might be do it. But you do a complicated Fontan operation, you need someone with a lot of years of experience to provide suction.
Q. Okay. Holding traction, how experienced --
A. Same, ten or more years. The more the better.
Q. I'm -- I'm trying to understand what you mean, though, when you say "ten or more years." Do you mean ten or more years out of medical school, or ten or more years out of your fellowship?
A. After -- after medical school, general surgery, cardiothoracic training, independent practice, et cetera. Everything.
MR. THOMPSON: Gotcha. I'm going to go ahead and end there, and I'm sure Mr. Brantingham's got some questions he wants to ask you.

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MR. BRANTINGHAM: Yeah. I've got a couple questions, doctor. Bear with me one moment. Sorry.
EXAMINATION
BY MR. BRANTINGHAM:
Q. I want to ask about the topics that Mr. Thompson was asking you about with regard to publishing -- or about this case or reporting some issue to the FDA or some other body. Do you --
A. Uh-huh.
Q. -- remember those questions?
My question for you is: Number one, there are -- are there internal procedures within Mayo or -- and/or within your department to review adverse events or complications?
A. Yes, we have the morbidity and mortality conferences and the quap -- I mean quality conferences to review the --
Q. Okay.
A. -- cases and look at the overall statistics.
Q. Okay. And I -- I'm not going to ask you to talk about any of the conclusions of the process because, as you understand, those are --

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are legally protected.
But with respect to this event and this case, did you follow Mayo procedures in regard to morbidity and mortality in review of the case?
A. Yeah. The case was presented.
Q. Okay. Let's leave it there.
Are there people at Mayo in charge of compliance and other issues related to reporting of events?
A. Yes. There's -- there's a whole team in the transplant center for -- to take care of compliance and report what needs to be reported.
Q. And do you rely on those people to determine what needs to be reported and -- and how and when?
A. Yes.
Q. Okay. Do you have any recollection of discussing potential use of -- of OCS with Mr. Leopold or -- and/or his family?
A. It --
I don't recall exactly the 30-minute conversation or so, but it is -- you know, in most of the cases I will tell them what type of procurement we would use, and if it will be the

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heart in a box -- I usually refer to the heart in a box -- and if the patient understands what's the heart in a box, then we, you know, tell the other patients. So most of the cases, you know, before I -- we go to transplant, I tell them, but I don't recall the 30-minute conversation from that day.
Q. Okay. So am I understanding it correctly that you're saying you don't remember specifically in this case, but in -- in many cases or in most cases you will --
A. Yeah.
Q. -- talk to patients about that?
A. Yeah. I'm almost -- probably in the --
When I talk to the people in the outpatient setting, in a hundred percent I'm -- get sure that I talk to -- to it, and -- and I would say very likely close to a hundred in the inpatient setting.
Q. Is there any, in your judgment, in your practice, is there any -- is there any risk concern associated with using OCS under the correct circumstances as compared to cold storage or cold transit?
A. Yeah. It is -- it has been shown so

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far equivalent results, and even equivalent results in more complex cases. So you take cases for farther away, if your recipient needs a more complex operation that would need to, you know, wait a long time, and any -- anything, you know, far away, any technical difficulty or -- you know, the OCS have shown equivalent results. Also, other type of donors, like the DCD donors, have shown equivalence to brain dead and cold storage -- versus cold storage heart transplantation.
Q. So is this --
A. Even in DCD, the most difficult of the donors.
Q. Okay. Is this a --
So is that something that you're telling patients is more risky, or -- or not?
A. No, because it's -- this have demonstrated the same results in more complex situations, so what I have told them that the -- the OCS TransMedics help us, you know, to go farther and to be, you know, safer in the most complex operations or in the most complex donors like -- like the DCDs and that will have equivalent results. And likely, you know, if

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they get it transplanted quicker, the waiting-list mortality of -- you know, will be decreased because you get access to more organs. Because what you want to avoid is to have -- to avoid waiting-list mortality, which is somebody in cardiogenic shock is a high risk of death, so you want to avoid the waiting-list mortality.
Q. Okay. I would like to ask about another topic. Mr. Thompson asked you some questions about OPTN guidance. Do you remember that?
A. Yes.
Q. And he read to you some language from an OPTN document, but he actually didn't show you the document; did he?
A. He didn't.
MR. BRANTINGHAM: I'm going to ask to just mark this OPTN document as Exhibit 1.
(Exhibit 1 was marked for identification.)
BY MR. BRANTINGHAM:
Q. If you look on that document, doctor, on the second page there's a header, Recommendations, and then a subheader, Deceased Donor Work Group Recommendations. Do you see

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that?
A. Yes.
Q. What does the language after number four on that list say?
A. "The following information should not be disclosed: Religion; specific diagnosis; ethnicity and race; sexual orientation; chronic illness unrelated to the donation; mechanism of injury or death."
Q. You answered some questions about whether you disclosed, I think, to the patient here the particular mechanism of this donor's death. Does, as far as you know, does this guidance apply to that question?
A. Yes, it does.
Q. And what does it mean?
A. It means that you cannot disclose that, because if I disclose it, I might be banned from my transplant practice.
MR. BRANTINGHAM: I have no further questions.
EXAMINATION
BY MR. THOMPSON:
Q. Your testimony is that you think that OPTN would ban you from your transplant practice

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if you told a patient that the donor heart had died of an intracranial hemorrhage.
A. Yes, they can do that.
Q. Yeah. Have you ever heard of that ever happening?
A. Yes. They have closed programs for poor compliance.
Q. For telling people that somebody died of an intracranial hemorrhage?
A. For -- for poor compliance.
Q. That wasn't my question.
A. And -- and I'll answer your question. This goes into -- there's a law, the HIPAA law, and they have been questioned, they have been sued and have to pay huge amounts of money for revealing confidential information and deceased-donor information.
Q. Okay. Both HIPAA and the OPTN Guidelines have to do with protecting donor anonymity; right?
A. Protecting what? Donor --
Q. Donor anonymity.
A. Yes.
Q. The whole reason that you're not supposed to disclose certain information is to

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make sure that the recipient and/or their family can't track down the donor; right?
A. Yes.
Q. Right? Explain to me how telling Noah Leopold that the donor was coming from a heart that had -- person who had died of an intracranial hemorrhage could possibly have led to them tracking down the donor.
MR. BRANTINGHAM: I think this has been asked and answered.
MR. THOMPSON: Not of him.
THE WITNESS: Yeah.
MR. BRANTINGHAM: Okay.
MR. THOMPSON: And you brought it up, foolishly, but you did.
MR. BRANTINGHAM: Well hold on a second. You're asking him a completely different subject here from what's in -- just written in that document.
MR. THOMPSON: No, I'm not at all.
MR. BRANTINGHAM: Okay. Go ahead. You can answer the question.
A. Well if the --
By word of mouth, the transplant professional can talk to each other about

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confidential information and the recipient can get to know where -- where is that, so they can identify them, the donor.
Q. How?
A. So they -- they can see who died, you know, in, you know, a period, and then talk to other people and talk to other people, and that's the way that things get usually distorted and that -- do not get it right and they do not get confidential.
Q. Yeah. We're going to stick, though, with the actual purpose of the regulation, and I thought you agreed with me, is to make sure that the recipient and/or his family can't track down the donor; right?
MR. BRANTINGHAM: Foundation.
A. No. They -- they --
The information should be confidential.
Q. Confidential in order to keep the donor's identity confidential; right?
A. Yes.
Q. Okay. So back to my question. Explain to me how telling Noah Leopold "Your donor heart is coming from somebody who died of an intracranial hemorrhage" could possibly lead to

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the donor being identified.
A. Yeah. From one person to another can -- the word of mouth, as I already said.
Q. Word of mouth --
A. And the other -- let me finish -- and the other thing that can happen, that family can black -- after they get to know after one year or more what happened, they can, you know, blackmail donors or vice versa to say about any confidential like, you know, this donor, we are going to let the people know that this human being, you know, was a drug addict and give -- you know, that information and blackmail people. So we want to avoid any, you know, extortion practices --
Q. Again, --
A. -- as well.
Q. -- in order for that to happen, the recipient's family would have to know who the donor is; right?
A. Yeah. They can find out.
Q. How? You haven't explained it to me. You said word of --
A. Well I did it. I did --
Q. Hold on. Hold on.

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MR. BRANTINGHAM: Let him finish the question.
Q. Let me finish my question.
You've said "word of mouth." Explain to me specifically, word of mouth between who and who is somehow going to lead this family in Florida to know specifically that this heart came from one individual person in Idaho that had an intracranial hemorrhage.
A. Let's -- let's say that there's friends, that one friend works in Idaho and other works at the Mayo Clinic --
Q. But they don't know it's coming from Idaho.
A. Well but they know there will be donor and they will match the time.
Q. How --
A. Yeah.
Q. Match what times?
A. Yeah.
Q. What are you talking about?
MR. BRANTINGHAM: Hold on one second. You're -- you're explicitly asking him to speculate. Now you're getting upset that he's speculating as you're asking him to, I mean --

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MR. THOMPSON: No. Because what he's saying is ridiculous. It's patently wrong and ridiculous.
A. No, no, no.
MR. BRANTINGHAM: Hold on. Just hold up. Just, doctor, hold up.
A. No, no, no. I don't --
Listen, --
Q. And I'm going to be incredulous about it.
A. -- I'm not going to accept any insults from you.
Q. Okay. So stick with my question.
A. Can you retract your insults?
Q. Stick with my --
No.
A. Can you retract your insult?
Q. What you're saying --
A. Don't insult me.
Q. What you are saying makes no sense to me, and so I am trying to figure out what it is that you're saying.
A. Well you have --
MR. BRANTINGHAM: Please let him explain.

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Q. First let me ask the question.
A. Yeah. I already answered to you. There could be somebody in the Idaho hospital that is a friend of somebody as a whole -- at Mayo that, you know, knows about the donor and they will -- can be talking to each other, so we cannot reveal any details of the case. And that is the way it's mandated and I don't have to explain it to you any further.
Q. Got it. You realize that even this part of the guidance that says cause of death should not be given, Mr. Brantingham didn't read the rest of that sentence, did he, where it says "unless the information is clinically relevant to the transplant recipient informed consent discussion." Do you see that part that Mr. Brantingham left out?
MR. BRANTINGHAM: I didn't actually read any of it. I had the witness read it, but --
Q. Oh, you left it out then.
A. I -- I read that, so all the relevant information was disclosed to Mr. Noah.
MR. BRANTINGHAM: And what's -- what's the language you're talking about? Because he

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read number four.
MR. THOMPSON: Right -- right. No. "specific age or circumstance of death..."
Oh, you had him read number four?
MR. BRANTINGHAM: Yeah. That's when you put the document in front of the witness.
Q. It's --
Isn't this also --
MR. THOMPSON: Stop. Stop.
Q. Are you telling me that you think that number four here overrules your legal obligation to provide informed consent to your patients?
A. I do prefer --
I do provide informed consent.
Q. Wasn't my question.
A. I don't know. I don't know.
Q. Okay.
A. I -- I provide informed consent to the patient. All the thing that you can do is speculation.
Q. All right. Let's do some more talk about informed consent.
You told Mr. Brantingham now after the break that hundred percent of the time, when you talk to a patient in an outpatient setting, you

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talk to them about the heart in a box.
A. Yes, sir.
Q. Okay. What do you tell them?
A. That there's, you know, different ways of preserving the heart; one is cold storage that allows four hours, and then we have OCS, you know, the heart in a box, that give us at least eight hours, but we don't know actually how long, and that's it.
Q. You don't tell them anything else.
A. It's a -- it's --
That it's a good tool that is equivalent to cold storage.
Q. Do you tell them about the results of the PROCEED trial?
A. Not as specifically.
Q. Why not?
A. Because if I have -- start talking about all the trials, you know, I'll finish, you know, in several years.
Q. I'm not talking about all the trials. I'm just talking about one trial.
A. Well this --
I mean if you see the literature, there's around 20 studies on heart

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transplantation with the OCS device. So I talk to each one, it will be completely irrelevant.
Q. Did you know that your friends at TransMedics specifically say physicians and patients should be aware of the results of the PROCEED trial?
MR. BRANTINGHAM: Object to the form of the question.
A. Yeah.
Q. Do you see that?
A. All right. I -- I haven't read this.
Q. Okay.
A. I --
Q. So this is --
A. But -- but --
MR. BRANTINGHAM: Just let him -- let him ask a question.
A. You ask me something. So but as, you know, I told you the answer that the study was equivalent, the PROCEED II trial says that it's equivalent.
Q. Okay.
A. So I, indirectly, I -- I tell them.
Q. Great. So now I'll ask you a different question.

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A. But I do not ask about the PROCEED.
Q. Right.
A. That would be completely irrelevant.
Q. Do you tell your patients that in the PROCEED trial overall survival was lower for OCS patients than in patients who were given hearts preserved with cold static preservation?
A. That's wrong. It's not significant.
Q. What's that?
A. That's wrong. It's not significant.
Q. Wrong and not significant.
Are you going to tell your friends at TransMedics that they should edit that part of their user manual that says physicians and patients should know about that?
MR. BRANTINGHAM: Object to the form.
Q. Go ahead and read it. I'm putting it in front of you like Mr. Brantingham wants me to. Read that bullet point to yourself. Read that whole thing and tell me when you're done.
A. (Witness complying.)
Well when I --
Q. Just --
Sorry. I told you to read it and tell me when you're done. Are you done?

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A. Yeah, I'm done.
Q. Do you comply with that?
A. They are not my governing tool, TransMedics.
Q. So is your answer "No, I do not comply with that?"
A. They -- I'm --
I do not have compliance issues with TransMedics, so I -- I -- there's no compliance with TransMedics.
Q. Do you do --
A. I'm a customer.
Q. Do you do what this part of the manual tells you to do?
A. Indirectly, yes.
Q. How?
A. When I said that it's around the same results.
Q. Right. You tell them something that's completely different and contradictory to what this tells you to tell them.
A. Well -- well you could read the whole article and you will see that there's no significant difference.
Q. Okay. Listen to my question, please.

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Is it your testimony --
A. Listen to my answer.
Q. Is it your testimony that when you advise patients about the OCS, you actually tell them something contrary to what the manufacturer advises you to tell them?
A. Well it's not contrary. It is that the -- it's lower, but it's not significant, so it needs more elaboration there to get the -- the fact to be truth. So it's not contradictory.
Q. When you meet with patients and tell them about the heart in the box, do you provide them with the OCS Heart System Patient Brochure?
A. No. I'm not --
Q. Do you --
A. -- not a representative of the company.
Q. Do you provide your patients with any written materials?
A. Probably the transplant coordinators, but I do not.
Q. Got it.
So "Patients should review the OCS Heart System Patient Brochure," you don't comply with that part either; do you?

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A. (Witness shaking head.)
Q. Your answer?
A. No, they are not a governing body. I do not do what their website says.
Q. Okay. This came off the FDA website --
A. Uh-huh.
Q. -- for your information.
A. Okay.
Q. So you don't do what the FDA website says.
A. Yeah.
MR. BRANTINGHAM: Well foundation and form.
Q. Well I can bring it up on the computer, but --
A. No. You told me that it was a TransMedics sign.
Q. No. I told you it's the TransMedics manual --
A. Well then --
Q. Hold on.
A. All right.
Q. We can't talk over one another.
A. Yeah. You should follow that advice to yourself.

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MR. BRANTINGHAM: Please go ahead and let's have a question. And just let him --
MR. THOMPSON: We do have a question.
MR. BRANTINGHAM: -- finish, doctor, and then let's have an answer.
Q. Go ahead and just read that to yourself and tell me when you're done.
A. (Witness complying.)
I'm done.
Q. You don't do that either; do you?
A. No.
Q. And the reason you don't do these things is because you're not governed by TransMedics; right?
A. I'm not governed by TransMedics, nope.
Q. TransMedics is good enough to pay for you to stay at the Ritz-Carlton in Saint Thomas, but not good enough to give you information about their own device to pass along to your patients.
MR. BRANTINGHAM: Hang on. I'll object to the form and the argumentative nature of the question. You can answer.
A. I went to investigators meeting in TransMedics. I'm interested in academic work

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and to provide life-saving, cutting-edge therapy to the patients. Other than that, there's no conflict of interest.

Q. Do you think TransMedics is a good company?

A. They have produced a device that have resulted in increasing -- in increasing heart transplants and increasing, you know, life-saving procedures. In that sense, they are a good company.

Q. Do you think that the device is a good device?

A. Yes, that's why I use it.

Q. Do you think it is a well-designed device?

A. Yes, I think it is well designed.

Q. So TransMedics has put out a well-designed, good device that you use for your patients all the time; right?

A. That is approved by the FDA.

Q. That's approved by the FDA as well.

Their manual is also approved by the FDA; is it not?

MR. BRANTINGHAM: Foundation.

Q. If you know.

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A. If you tell me, I can't -- I have no reason not to believe you.

Q. When you were at this meeting in Prague, were you there with Dr. Knop?

A. I don't remember if he went or not.

Q. I will tell you that he testified under oath this morning that he attended the International Society of Heart and Lung Transplantation meeting in Prague. That's the same meeting that you were talking about when somebody from TransMedics came up to you and said some lawyer's been sniffing around; right?

MR. BRANTINGHAM: Object to form.

A. Well again, I don't have any reason not to believe you. You're making a statement. I have no reason not to believe you that Knop -- Dr. Knop went to Prague to the IHLT meeting.

Q. Dr. Knop testified that during one of the question-and-answer sessions he got up and he actually provided information about what happened in this case. Did you know that?

A. I didn't know that.

Q. So you must not have been at that question-and-answer session.

A. Not that I remember.

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Q. Were there other Mayo folks from your department who were at the meeting?

A. I remember Dr. Spencer was there.

Q. Uh-huh.

A. From lung transplant, Dr. Saddoughi.

Q. Do you know if this directive that you gave to the people who wanted to do the case report to keep this whole thing under wraps went to Dr. Knop as well?

MR. BRANTINGHAM: Object to the form of the question.

A. That was -- that was not the directive.

Q. The directive was "We're not going to publish anything about this outside of Mayo until the lawsuit's over."

MR. BRANTINGHAM: Object to form. You can answer.

A. Yeah. Let's -- let's wait.

Q. Okay. So the directive to not talk about this outside of Mayo until the lawsuit's resolved, was that passed on to Dr. Knop as far as you know?

A. I don't know about that. I remember he --

I don't remember him doing the case-

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report work. I remember the transplant fellow and a guy from intensive care that I don't remember his name, but I don't know anything about Dr. Knop.

Q. And you told me --

A. In terms of case reports.

Q. Do you remember the name of the transplant fellow?

A. Yeah, actually. Chauhan.

Q. Spell that for us, please.

A. A-k-s-h-a-i space C-h-a-u-h-a-n.

Q. Is that a he or a she?

A. He.

Q. Is he still here at Mayo?

A. No. He finished his transplant fellowship.

MR. BRANTINGHAM: It's the one in the medical record that you've asked about.

MR. THOMPSON: That's the one that we're -- yep. Got it.

Q. The cardiology person who wanted to do a case report, do you remember his or her name?

A. No. They are -- you --

Intensive care I think is most likely, not cardiology, intensive care fellow. I

don't -- I don't remember.

Q. Do you --

A. But I remember receiving an email about data. I said wait, please.

Q. You got an email from them about it.

A. Yeah.

Q. And did you respond via email as well?

A. Yeah, yeah. The -- I believe so. Yeah.

MR. THOMPSON: I'll go ahead and request that. All right.

MR. BRANTINGHAM: I didn't totally track the description of it, but I'm sure that you will send a follow-up communication.

(Discussion off the record.)

BY MR. THOMPSON:

Q. If the family, Noah's family, testifies that neither you nor anybody else told them anything about the OCS, are you going to deny that?

A. I, again, you know, I cannot be a hundred percent sure, but very likely I talked to him about it.

MR. THOMPSON: All right. I don't have any other questions.

MR. BRANTINGHAM: I don't have any questions. We will read and sign.

THE REPORTER: Okay. Thank you. Off the record.

(Deposition concluded at 4:17 p.m.)

C E R T I F I C A T E

I, Nicole A. Huber, hereby certify that I am qualified as a verbatim shorthand reporter; that I took in stenographic shorthand the testimony of MAURICIO VILLAVICENCIO at the time and place aforesaid; and that the foregoing transcript consisting of 151 pages is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Baxter, Minnesota, this 20th of August, 2024.

NICOLE A. HUBER
Notary Public

S I G N A T U R E P A G E

I, MAURICIO VILLAVICENCIO, the deponent, hereby certify that I have read the foregoing transcript, consisting of 151 pages, and that said transcript is a true and correct, full and complete transcription of my deposition, except per the attached corrections, if any.

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Date Signature of Witness

WITNESS MY HAND AND SEAL this _____ day of _____, 2024.

(NAH) _____

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